US PATENT APPLICATION
Docket No. WILB01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: BRIAN R. WILL

Serial No.	10/608,408	Examiner:	Shay, David M.
Filed:	June 27, 2003	Group Art Unit:	3735

For: EYE FIXATION APPARATUS

Date: April 14, 2008

Mail Stop RCE
The Honorable Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AFFIDAVIT UNDER RULE 1.132 TRAVERSING REJECTIONS

I, BRIAN R. WILL, hereby declare under penalty of perjury based on personal first hand knowledge the following to be true and accurate:

1. I write this declaration to overcome and traverse rejections made under Section 103 in the April 11, 2007 Final Office Action. This declaration is submitted in conjunction with a Request for Continued Examination. Applicant timely filed a Notice of Appeal on June 22, 2007, and timely filed Appeal Briefs, but has withdrawn the Appeal in order to submit new evidence into the record for consideration.

2. I have previously submitted a declaration under Rule 1.132, dated January 10, 2007. I reiterate the statements and arguments made in that prior declaration and hereby incorporate those statements by reference.

3. I am a board certified Ophthalmologist with over 17 years of practice. I have performed over 28,000 LASIK procedures as well as over 10,000 other ocular procedures in that time, and currently perform over 3,000 LASIK procedures per year. I have intimate experience with much of what has been considered state of the art in the field of LASIK and other keratome procedures, using lasers and microkeratome blades, including the devices incorporating the features of Hellenkamp (U.S. 6,042,594), Clark (U.S. 5,591,174), Curtin (U.S. 4,173,980) and L'Esperance (E.P. 0372127A1) references, or similar to these references, cited by the Examiner. This declaration is made based on my personal experience and that of my staff of two (2) ophthalmologists within the field, whom I personally supervise.

4. My staff ophthalmologists and I meet regularly to discuss patient outcomes and to evaluate procedures and conduct training.

5. The Examiner has expressed skepticism that prior art devices using annular vacuum rings such as described in Hellenkamp cause complications in patients undergoing LASIK and other surgical procedures. My descriptions of the drawbacks of existing known devices are not "speculative", but are a subject of growing concern with an increasing body of research and literature investigating these issues.

6. Attached as Exhibit 1 is a true and correct copy of an article, Jose L. Hernandez-Verdejo, Miguiel A. Teus, Jose M. Roman, Gema Bolivar, PORCINE MODEL TO COMPARE REAL-TIME INTRAOCULAR PRESSURE DURING LASIK WITH A MECHANICAL MICROKERATOME AND FEMTOSECOND LASER, *Investigative*

Ophthalmology & Visual Science, January 2007, Vo. 48, No.1. The intent of the authors was to compare the elevation of intraocular pressure (IOP) caused by the flap-cutting portion of LASIK procedures using a mechanical microkeratome blade versus laser microkeratome cutter. At page 1, the authors note that there is a widespread concern about the damage caused to eye structures from the increased IOP during LASIK and other procedures. The authors note that several hypothesis focus on the "suction ring" used to fix the eye during procedures. "Different hypotheses explain the posterior segment complications, with the first postulating that the mechanical stress is caused by the IOP elevation produced by the pneumatic suction ring, which may induce tangential stress on the posterior segment." Id at p.68, col 2. The authors note that real-time measurement of changes in IOP during LASIK and other procedures have been difficult to measure in the past. Id. During the experimental procedures the IOP of the porcine eyeballs was recorded continuously. Id at p. 69, col 2. "Both groups [mechanical and laser flap cuts] had an IOP increase immediately after the placement of the suction ring that was maintained during the entire surgical procedure." Id p.70, col 2. The authors noted another study which demonstrated analogous significant rises is IOP using single-port versus two-port suction rings. Id at p.70, col 2. The authors' noted that "...pressure setting for the suction ring is an important variable in determining consistent corneal flap thickness during LASIK" and that lower vacuum settings tend to produce lesser increases in IOP. Id. pp. 70-71. "Sudden increases in IOP, although well tolerated, may induce changes in the peripheral retina... These possible posterior segment

complications, among others, make the knowledge of the exact IOP increase induced by surgical procedures such as laser refractive surgery increasingly important."

a. The authors do not specify that the suction rings used were based on Hellenkamp, but in the field of ophthalmologic surgical procedures the term "suction ring" is generally understood to refer to a vacuum annulus design, essentially the same as taught in Hellenkamp. Vacuum annulus designs are the industry standard at this time.

7. Attached as Exhibit 2 is a true and correct copy of an article, Wei-Li Chen, Yung-Feng Shih, Shu-Lang Liao, Fung-Rong Hu, Por-Tying Hung, ULTRASOUND BIOMICROSCOPIC FINDINGS IN RABBIT EYES UNDERGOING SCLERAL SUCTION DURING LAMELLAR REFRACTIVE SURGERY, *Investigative Ophthalmology & Visual Science*, December 2002, Vol. 43, No. 12. The purpose of the study was to evaluate changes in corneal structure caused by changes in IOP due to application of scleral suction rings. Suction ring related complications during lamellar refractive surgeries (including LASIK) included retinal vascular occlusion, ischemic optic neuropathy, and macular hemorrhages due to elevated IOP during surgery, and subconjunctival hemorrhage – caused by application of the suction ring. Id at 3669, col 1. The authors concluded that the application of the suction ring itself causes harm to a subject's eye, and that the amount of damage correlated to the length of time the suction ring was applied. The damage was due to the stresses induced by the deformation of the eye itself and

consequent rise in IOP, as well as the effect of the suction ring on the scleral surface displacing into the suction ring volume. Id at pp. 3670-71.

8. Attached as Exhibit 3 is a true and correct copy of an article, Alireza Mirshahi, MD, Thomas Kohnen, MD, EFFECT OF MICROKERATOME SUCTION DURING LASIK ON OCULAR STRUCTURES, *Ophthalmology*, April 2005, Vol. 112, Nr. 4. The purpose was, "To study the effect of microkeratome suction on ocular structures during LASIK." The procedures were conducted using a 20.3 mm suction ring. Id at p.646, col 1. "The mechanics of microkeratome suction can be compared to that of blunt ocular trauma when the ocular globe is compressed and quickly released... however, at a much lower level incidence and degree." Id at p.648, col 2. The authors noted that more study is required to understand the precise causes. Thus, this article corroborates my belief that existing suction ring designs are a source of trauma to the eyes of patients undergoing LASIK procedures. My invention addresses what I believe to be part of the cause of this trauma – the displacement of the sclera into the high chamber of suction ring designs such as Hellenkamp, and the deformation of the eyeball caused by these designs, which draw the eyeball up and into the central opening for cutting of the keratome flap.

a. The authors describe increased IOP as desirable "creating a firm cornea and permitting a precise corneal flap to be cut, which is followed by laser ablation." Id at p.645. Thus, the conventional literature can be said to teach away from my invention, in that my design seeks to reduce eyeball

deformation and minimize the rise in IOP caused by the eye fixation device.

9. Attached as Exhibit 4 is a true and correct copy of an article, Christina J. Flaxel, MD, Young H. Choi, MD, Michael Sheety, MD, Stephen Christopher Oeinck, CRA, Joe Y. Lee, MD, Peter J. McDonnell, MD, PROPOSED MECHANISM FOR RETINAL TEARS AFTER LASIK, *Ophthalmology*, 2004; Vol. 111, pp. 24-27. The suction ring used in the study was described: "The suction ring is a circular chamber that fixates the eye by means of a vacuum. The underside of the fixation ring has a vacuum chamber that seals against the globe." Id at p. 26, col. 1-2. This matches the description of the devices in Hellenkamp and Curtin/Clark and is indicative of existing devices. The authors concluded that the mechanics of the suction ring itself may be a source of damage to eyes of patients with pre-existing vulnerabilities.

10. Attached as Exhibit 5 is a true and correct copy of an article, Julie M. Albietz, PhD, Lee M. Lenton, Suzanne G. McLennan, DRY EYE AFTER LASIK: COMPARISON OF OUTCOMES FOR ASIAN AND CAUCASIAN EYES, *Clinical and Experimental Optometry*, March 2005, vol 88.2. The purpose was to investigate anecdotal evidence that LASIK patients of Asian decent experienced higher incidences of complications such as Dry Eye after LASIK. The authors found that Asian LASIK patients did suffer higher incidence of dry eye, with several potential contributing causes. One cause discussed was the smaller ocular orbit and tighter lids generally found in Asian patients compared to Caucasian patients. Id at p. 95. The tighter lid structure led to a higher incidence of flap cut

complications and longer intra-operative prep times leading to greater damage to the ocular surface were due in large part to the tight fit of the suction ring between the lids. Id at p. 95.

a. Applicant submits that one of the advantages of the low profile apparatus of the present Application is that it fits under the eyelids of patients. Thus, the lids must accommodate only the narrow central access hole for the microkeratome blade or laser access (approximately 9-12mm) rather than the full diameter of the vacuum ring (approximately 20mm +/-, see Exhibit 3 and paragraph 7, above).

b. Longer intraoperative prep times translates into longer application of vacuum to the suction ring, which as discussed in Exh. 2 and paragraph 6, above, seems to lead to increased trauma to the ocular surface and anterior structures.

11. Attached as Exhibit 6 is a true and correct copy of an article, Jane-Ming Lin, MD, Yi-Yu Tsai, MD, RETINAL PHLEBITIS AFTER LASIK, *Journal of Refractive Surgery*, September/October 2005, Vol. 21, p.501. The authors provide a case study of a patient suffering retinal phlebitis due to LASIK complications. The authors concluded that the cause of the retinal phlebitis may have been due to the negative effects of elevated IOP caused in part by the

suction ring. The authors note that standard practice is to achieve an IOP of at least 65mmHg to support mechanical keratome flap cutting. Id at 502, col 2.

12. The Exhibits discussed above, as a whole, demonstrate that the existing industry suction rings, which are essentially versions of those described in Hellenkamp and Curtin/Clark, are known to be problematic in LASIK procedures although this was not known at the time of the Hellenkamp reference. The present invention seeks to reduce the damage caused by suction ring devices such as described in Hellenkamp, which are commonly used in ophthalmologic surgery.

13. Regarding the porous membrane and high profile chamber of L'Esperance, I am of the opinion, based on over 17 years of experience in the field and having personally performed thousands of LASIK procedures, and having trained and supervised dozens of other doctors in the procedures, that the porous membrane system is subject to a number of drawbacks. Among other things, it is my professional opinion that the porous membrane with vacuum on one side and mucus on the other would be subject to frequent clogging and be difficult or impossible to properly clean and sterilize. The fact that, with extensive personal experience in this field, I am not familiar with any vacuum fixation device using the L'Esperance porous membrane system supports my opinion. If the L'Esperance membrane were effective then surgeons would use it, and I have not seen surgeons use such a device. The nature of the L'Esperance device also requires a high profile vacuum chamber. That is what is taught by L'Esperance and I see no other way to use the L'Esperance system without

extensive modifications. Therefore, all of the problems I have described, and which are supported in the professional literature, relating to high profile devices would apply especially to L'Esperance.

14. I also address the Examiner's prior stated skepticism regarding the need for lid specula when using high profile suction rings such as described in Hellenkamp, Curtin/Clark and L'Esperance. A high profile suction ring will actually not fit into many patients' eyes as their lid fissures are simply not large enough to accept the diameter or high profile vacuum ring required. The vacuum fixation device described in L'Esperance appears to have even worse features. The inability to accept high profile suction rings is particularly true for patients of Asian descent, and smaller people (females more frequently than males). With high profile apparatus described in Hellenkamp and L'Esperance the surgery either cannot be performed on such patients, or the patient must have their eyelids cut open and then sutured back together at the completion of the surgery. This significantly increases the risk of the surgeries, and leads to longer healing times for the patients.

15. In many, many cases where the lids are very tight, although we can complete the surgery, the patient experiences excessive pain because we have had to stretch the lid tissues in order to place the suction ring. This stretching may lead to permanent damage to the delicate lid tissue (skin, tendons and muscles) and result in development of "droopy" lids or redundant skin on the eyelids over the longer term. Such conditions would require additional surgery to repair. These are medical facts that any experienced refractive surgeon would be

aware of and are outlined to the patient in every surgical consent form. In contrast, the low profile vacuum ring of the present Application allows much of the footprint of the vacuum fixation device to be inserted *under* the lids, thereby allowing surgery to be performed without these difficulties or long term risks. The low profile is achieved through the use of the criss-cross vacuum channels, which are elements of all claims. Claim 22 explicitly claims a low profile apparatus, with criss-cross channels, which fits under the eyelid to obviate the need for a lid speculum.

16. Other problems with high profile suction rings, such as described in Hellenkamp and L'Esperance, lead to difficulties in carrying out the surgery itself. A high profile suction ring allows the patients' eyelids to gain more purchase, or force, on the ring. In a patient that is squeezing hard, they may dislodge the ring during the operation, which can result in irreversible eye damage in the worst case. As a result, a lid speculum is nearly mandatory when using suction rings described in Hellenkamp and L'Esperance so as to control lid pressure. The low profile device described in the present Application causes a lower level of distention of the sidewall of the eye, so the patient will not likely feel the same level of pain or pressure and so will be less likely to squeeze their lids together (and therefore less likely to displace the suction ring and less likely to cause long term damage to the lid tissues). Equally important, the eye lids cannot obtain the same level of tension on the edge of the low profile vacuum ring and this markedly diminishes the need for a lid speculum and reduces the potential for

serious intraoperative complications. The low profile device avoids this because eye lid slips comfortably over the vacuum footprint of the device.

17. The low profile of my apparatus, as described in the claims, is achieved through the use of the criss-cross channel design. The criss-cross channels allow the use of shallower vacuum channels and distribute the vacuum over a greater area, allowing reduced vacuum levels. The Exhibits 1-6, discussed above, all discuss the damage caused to the eye structures by higher vacuum applied through suction rings similar to Hellenkamp.

18. I would also like to address an issue which I have not previously addressed. The present literature, such as discussed in Exhibits 1-6, addresses both the damage caused by elevated IOP, as well as the desirability of elevated IOP in order to tension the cornea for cutting the flap. My invention teaches an opposite approach – to improve the accuracy of flap cuts and corneal shaping by minimizing the increase in IOP during the vacuum fixation and flap cutting portion of the procedure. As I have explained previously, the present apparatus and methods seek to achieve higher accuracy by reducing distortion of the eyeball and changes in hydration of the cornea caused by suction rings such as described in Hellenkamp. Thus, the references cited by the Examiner actually teach away from the apparatus and methods which I am claiming.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that

willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

DATED THIS April 14, 2008

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Porcine Model to Compare Real-Time Intraocular Pressure during LASIK with a Mechanical Microkeratome and Femtosecond Laser

José L. Hernández-Verdejo,[1,2] *Miguel A. Teus,*[1,3] *José M. Román,*[1] *and Gema Bolívar*[3]

PURPOSE. To compare real-time intraocular pressure (IOP) during laser in situ keratomileusis (LASIK) in porcine eyes using two types of microkeratomes.

METHODS. An interventional, prospective study of two microkeratomes: a Moria 2 (Moria group) and an IntraLase femtosecond laser (IntraLase Corp., Irvine, CA; IntraLase group). These devices were used to create lamellar corneal flaps in freshly enucleated porcine eyes. The IOP changes induced by the procedures were recorded with a reusable blood pressure transducer connected to the anterior chamber by direct cannulation.

RESULTS. Seven porcine eyes were studied in each group. The IOP increased during the suctioning phase, reaching a mean of 122.52 ± 30.40 and 160.52 ± 22.73 mm Hg during the cutting phase in the Moria group (the total time in this group was 36.42 ± 7.48 seconds; suctioning required 21.42 ± 7.48 seconds and the cutting phase, 15 ± 2.88 seconds). In the IntraLase group, the IOP reached 89.24 ± 24.26 mm Hg during the suctioning phase and 119.33 ± 15.88 mm Hg during the intrastromal laser application (the total time was 92.85 ± 13.49 seconds; suctioning required 40.00 ± 9.57 seconds and the cutting phase 52.85 ± 5.66 seconds). Both IOPs during both phases differed significantly between the two groups ($P = 0.01$ for all comparisons).

CONCLUSIONS. Real-time IOP can be measured during LASIK using a transducer connected to the anterior chamber. The results showed a significant increase in IOP during the procedure in both groups, although with the IntraLase the IOP seemed to increase to a lesser extent than with the conventional mechanical microkeratome. (*Invest Ophthalmol Vis Sci.* 2007;48:68-72) DOI:10.1167/iovs.06-0192

Laser in situ keratomileusis (LASIK) has become the most frequently performed corneal refractive surgery for the correction of low to moderate myopia. The procedure involves preparation of a superficial flap by using a mechanical keratome and ablation of the corneal stromal tissue with an excimer laser.[1]

Femtosecond laser technology enables nonmechanical creation of a corneal flap.[2-4] This technology includes a solid-state laser used to create flaps during LASIK. The laser uses an infrared wavelength (1053 nm) to deliver closely spaced 3-μm spots that can be focused to a preset depth to photodisrupt tissue within the corneal stroma. The resultant plasma produces cavitation bubbles, consisting primarily of water and carbon dioxide. The IntraLase femtosecond laser system (IntraLase, Corp., Irvine, CA) relies on a low-pressure (35 mm Hg) suction ring to align and stabilize the globe. A flat lens attached to the laser delivery system is used to applanate the cornea within the suction ring. To create the ideal corneal flap during LASIK, sufficiently high intraocular pressure (IOP) is needed to manage the eye.

Two different ways to measure IOP during corneal refractive surgery have been proposed; both have some drawbacks. Applanation tonometry cannot be performed when the microkeratome is cutting the flap. In addition, the viscosity of the vitreous gel may jeopardize IOP measurement in direct cannulation of the vitreous cavity.[5-7] For this reason, we recorded the real-time IOP by direct cannulation into the anterior chamber, to obtain accurate IOP measurements during LASIK.

The real intraoperative IOP that is achieved during the suctioning and the cutting phases and the differences in IOP that can occur if the flap is created with a mechanical keratome or with the IntraLase femtosecond laser have not been measured during surgery. High IOP and sudden changes in IOP may cause irreversible changes in ocular tissue.

The anterior segment complications of LASIK have been well documented in the literature.[8] In addition, there have been several reports proposing a casual relationship between LASIK and retinal detachments in myopic eyes[9-11]; macular hemorrhages, macular holes, lacquer cracks, and choroidal neovascular membranes developed after LASIK have also been reported.[12] Different hypotheses explain the posterior segment complications, with the first postulating that the mechanical stress is caused by the IOP elevation produced by the pneumatic suction ring, which may induce tangential stress on the posterior segment.[13] Some investigators have proposed that the shockwave generated by the impact of the excimer energy on the cornea can generate pressure of up to 100 atmospheres, which also causes mechanical stress on the eye.[14] Acute damage to the optic nerve after LASIK has also been reported.[15]

Some case studies have reported that this increase in IOP damages the retinal ganglion cells, causing visual field defects.[16] Other studies have reported that the retinal nerve fiber layer thickness decreases after uncomplicated LASIK[17,18] or even that LASIK could cause occlusion of the retinal arteries.[19]

To the best of our knowledge, there are no published studies of the real-time IOP changes during a femtosecond laser procedure compared with IOP changes induced during a conventional mechanical LASIK procedure, especially when the IOP is measured via the anterior chamber.

The purposes of this study were to develop an experimental model to measure real IOP changes using an external manometer connected to the anterior chamber and then to compare these changes when using two well-known methods, a mechanical keratome and low-pressure IntraLase technology, to perform LASIK.

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Disclosure: **J.L. Hernández-Verdejo**, None; **M.A. Teus**, None; **J.M. Román**, None; **G. Bolívar**, None

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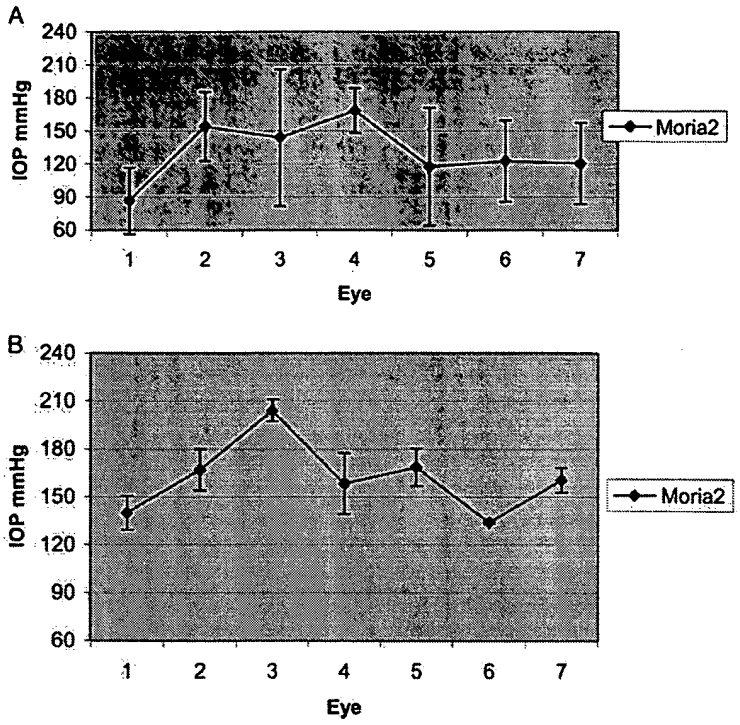

FIGURE 1. Mean IOP ± SD in each eye in the Moria group during the suctioning (A) and cutting (B) phases. IOPs were recorded every 5 seconds from the exact moment that the suction ring was applied. The mean time was 21.42 ± 7.48 seconds in the suctioning phase and 15.00 ± 2.88 seconds in the cutting phase.

MATERIALS AND METHODS

In this experimental model, using porcine eyes, we prospectively evaluated the changes in IOP from the application of the suction ring through the end of the passage of the mechanical microkeratome (M2; Moria, Antony, France) or creation of the nonmechanical flap with the femtosecond laser (IntraLase Corp., Irvine, CA).

Fourteen freshly enucleated porcine eyes were separated into two groups of seven eyes each: the Moria group and the IntraLase group. All eyes were free of corneal damage when inspected by slit lamp microscopy.

The eyes were inflated with a 5% glycosylated solution through the optic nerve (in the same manner described by Kasetsuwan et al.[6]) to obtain an IOP of 8 to 20 mm Hg checked with a Perkins applanation tonometer; the eyes were placed on a stand with sufficient support to withstand the surgical procedure. The IOP was measured in the anterior chamber using a 27-gauge winged infusion (Set REF 387412 Valu-Set BD Biosciences, Hull, UK) that was inserted through the limbus in such a way that the suction ring could be applied over the sclera without touching the needle. Pressure measurements were obtained with a reusable blood pressure transducer (MLT0380 Reusable BP Transducer, Power Laboratory; AD Instruments, Racine, WI). The transducer is an external sensor for coupling to vascular pressure (in our experiment the IOP in the anterior chamber) via a liquid-filled catheter. A saline-filled silicone tube attached to the catheter was connected to the transducer. The transducer was prepared according to the instructions of the manufacturer, to assure a tight seal and that all air was flushed from the system. The recorder was set to 0 to initialize the transducer. Before starting the procedure, the transducer was checked to verify that the pressure would be registered correctly. For calibration, we connected the transducer to a mercury-calibrated column and then checked that the pressure in the mercury column and the display connected to the transducer were the same.

The suction ring was applied, and a flap was created in the eyes in both groups. The same experienced surgeon (JMR) performed all procedures on 1 day under direct microscopy visualization. During the procedure, the IOP was recorded continuously with the amplifier (ML110 Bridge Amplifier; AD Instruments, Castle Hill, Australia) connected to the barometric transducer, from the time of the application of the suction ring through the end of the microkeratome pass. IOP also was measured before and after the suction ring was placed, by using a Perkins handheld tonometer (Clement Clarke, Essex, UK). The IOP level after the procedure had to be at least 6 mm Hg, to rule out any substantial fluid leakage from the eye during the experiment.

Statistical analysis was performed using Student's *t*-test and the nonparametric Wilcoxon signed-rank test. $P < 0.05$ was considered significant.

RESULTS

Seven porcine eyes were studied in each group. In the Moria group, the mean IOP during suction was 122.52 ± 30.40 mm Hg (Fig. 1A) compared with 89.24 ± 24.26 mm Hg in the IntraLase group ($P = 0.001$). During flap creation, the mean IOP was 160.52 ± 22.73 mm Hg in the Moria group (Fig. 2A) compared with 119.33 ± 15.88 mm Hg in the IntraLase Group (Fig. 2B; $P = 0.001$).

The actual IOP immediately before suctioning was 11.5 ± 3.43 mm Hg ($r = 8$–16) in the IntraLase group and 17.28 ± 3.25 mm Hg ($r = 11$–20) in the Moria group. The IOP recorded by the transducer immediately after the maneuvers was 8.85 ±

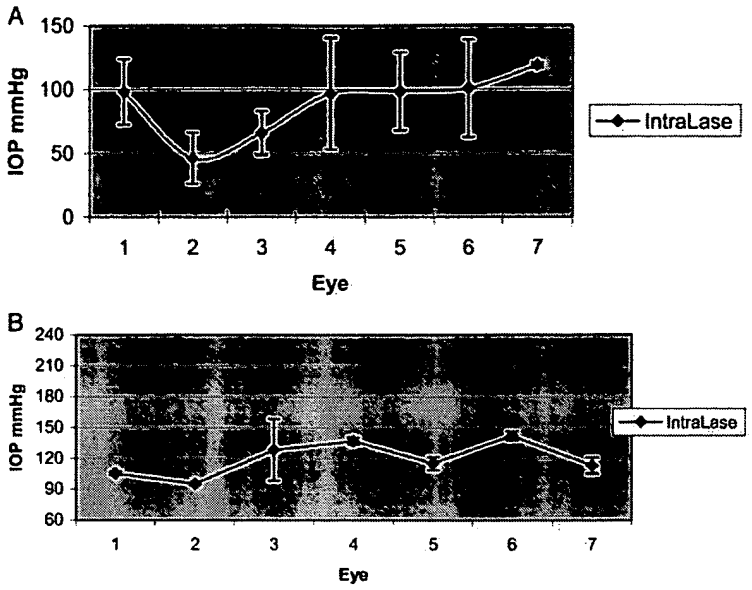

FIGURE 2. Mean IOP ± SD in each eye in the IntraLase group during the suctioning (A) and cutting (B) phases. The IOP was recorded every 5 seconds from the exact moment that the suction ring was applied. The mean time was 40 ± 9.57 seconds in the suctioning phase and 52.85 ± 5.66 seconds in the cutting phase.

2.11 mm Hg (r = 7 to 12) in the IntraLase group and 13.71 ± 3.63 mm Hg (r = 7 to 18) in the Moria group.

The mean time required to complete the suctioning was 21.42 ± 7.48 seconds (range, 15-35 seconds) in the Moria group compared with a mean of 40 ± 9.57 seconds (range, 30-55 seconds) in the IntraLase group (P = 0.04). The mean time needed to create the flap was 15.00 ± 2.88 seconds (range, 15 to 20 seconds) in the Moria group compared with 52.85 ± 5.66 seconds (range, 50 to 65 seconds) in the IntraLase group (P = 0.008; Fig. 3, Tables 1B, 2B).

The total time needed to complete the procedure in the Moria group was 36.42 ± 7.48 seconds and in the IntraLase group was 92.85 ± 13.49 seconds. The IntraLase procedure took twice as long as the mechanical procedure (P = 0.001).

DISCUSSION

In this animal model, we measured the real IOP in enucleated porcine eyes with two suction and cutting procedures during LASIK. Both groups had an IOP increase immediately after the placement of the suction ring that was maintained during the entire surgical procedure. We found differences both in suction time and in the real IOP levels that were achieved in both groups.

Bissen-Miyajima et al.[5] measured the IOP changes during LASIK using a direct method in porcine eyes. In that experiment, an intravenous pressure sensor was inserted into the vitreous cavity, whereas in our study the sensor was introduced into the anterior chamber. Despite this design difference, the study performed by those investigators showed a mean IOP increase of 99.1 ± 6.1 mm Hg, measured by a single-port suction ring and 99.0 ± 6.5 mm Hg using a dual-port suction ring during mechanical microkeratome use. In another study performed in human cadaveric eyes,[6] the measurements were obtained by entering the vitreous cavity through a pars plana incision. The results at two vacuum-pressure settings (488 and 600 mm Hg) after application of the suction ring alone were 93.3 ± 2.6 mm Hg for the 488-mm Hg

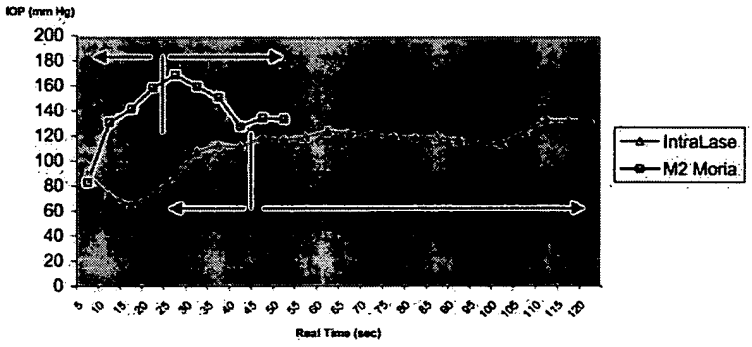

FIGURE 3. IOP increases in mm Hg over time, measured every 5 seconds, in both groups of seven eyes each, in the Moria mechanical microkeratome group and the IntraLase group. *Vertical lines*: the exact moment at which the cutting began. Suction time, 21.42 ± 7.48 seconds in the Moria group and 40 ± 9.57 seconds in the IntraLase group; cutting or flap time, 15.00 ± 2.88 seconds in the Moria group and 52.85 ± 5.66 seconds in the IntraLase Group.

TABLE 1. Moria Group

A. IOP Increases in IOP in Each Eye from Application of the Suction Ring to the End of Flap Creation

Eye	Mean (mm Hg)	SD	Range
1	106.5	±36.39	40-148
2	160.5	±22.66	120-182
3	173.83	±51.52	72-208
4	161.67	±21.52	127-182
5	140.75	±52.94	60-219
6	125.8	±30.61	47-147
7	131.71	±36.09	62-166

B. IOPs Recorded during the Study

Eye	IOP Pre	IOP Suction	IOP Cut	IOP Post	Suction Time (s)*	Cutting Time (s)*
1	15	86.4	140	11	25	15
2	20	154	167	14	15	15
3	20	89	204	16	15	15
4	18	168.3	155	15	15	15
5	11	117.5	164	7	20	20
6	18	122.28	134	15	35	15
7	19	120.2	159.66	18	25	10
Mean	17.28	122.52	160.52	13.71	21.42	15
SD	3.25	30.4	22.73	3.63	7.48	2.88

Initial IOP (IOP pre), mean IOP (in mm Hg) of the suctioning phase (IOP Suction), mean IOP of the cutting phase (IOP Cut), and final IOP (IOP Post) immediately after the cutting phase for each of the seven eyes.

* The two columns on the right show the suctioning and cutting time for each eye expressed as the mean ± SD.

group and 108.0 ± 22.1 mm Hg for the 600-mm Hg group; during the microkeratome pass, the mean IOP was 82.0 ± 15.0 mm Hg for the 488-mm Hg group and 92.5 ± 38.8 mm Hg for the 600-mm Hg group. The pressure changes during the microkeratome pass were not statistically significant. The lower levels of IOP found in those two studies may reflect the fact that the velocity at which the pressure is transmitted in a fluid-filled tube depends on the fluid viscosity, and it therefore seems reasonable to consider that the measurements registered through the anterior chamber, as in the present study, should be more precise than those obtained through the vitreous chamber.

In our study, the IOP increased in both groups, although it followed a different pattern. For example, in the Moria group, the mean IOP increase during suctioning was 122.53 ± 30.40 mm Hg and reached a mean 160.52 ± 22.73 mm Hg during the creation of the lamellar corneal flap. We also observed a great deal of fluctuation in the IOP levels. However, in the IntraLase group, the mean IOP during suctioning was 89.24 ± 24.57 and 119.0 ± 17.01 mm Hg during the flap creation. In this case, the

TABLE 2. IntraLase Group

A. IOP Increases in IOP in Each Eye from Application of the Suction Ring to the End of Flap Creation

Eye	Mean (mm Hg)	SD	Range
1	101.75	±18.02	(59-129)
2	76.69	±35.72	(34-114)
3	99.54	±33.84	(36-132)
4	109.06	±35	(45-160)
5	107.72	±21.54	(70-141)
6	127.35	±30.1	(72-157)
7	115.35	±3.18	(112-122)

B. IOPs Recorded during the Study

Eye	IOP Pre	IOP Suction	IOP Cut	IOP Post	Suction Time (s)*	Cut Time (s)*
1	13	98.2	105.3	11	50	50
2	9	46.16	95	9	30	50
3	8	65.72	128.15	6	55	65
4	8	96.87	136.8	7	40	50
5	15	98.5	115.1	9	40	50
6	16	100.66	141.9	12	30	55
7	9	118.57	113.1	8	35	50
Mean	11.5	89.24	119.33	8.85	40	52.85
SD	3.43	24.26	15.88	2.11	9.57	5.66

The initial IOP (in mm Hg; IOP Pre), mean IOP of the suctioning phase (IOP Suction), mean IOP of the cutting phase (IOP Cut), and the final IOP (IOP Post) immediately after the cutting phase for the seven eyes.

* The two columns to the right show the suctioning and cutting time for each eye expressed as the mean and standard deviation.

IOP increase was more stable throughout the procedure, especially during the cutting of the flap.

Previous studies have reported that the LASIK flap may induce higher-order aberrations (HOAs) and advocate the use of photorefractive keratectomy for wavefront-guided treatments.[20] Recently, Durrie and Kezirian[21] reported that the IntraLase femtosecond laser induces fewer HOAs, less residual spherical equivalent, and less residual astigmatism, and has better predictability than does photorefractive keratectomy. Kasetsuwan et al.[6] showed that the pressure setting for the suction ring is an important variable in determining consistent corneal flap thickness during LASIK. An interesting aspect of our study was that the IOP levels achieved during the IntraLase procedure were lower and more stable than those achieved when creating a flap with a mechanical microkeratome.

Sudden increases in IOP, although well tolerated, may induce changes in the peripheral retina, as described by Charteris et al.,[10] Krueger et al.,[14] and Flaxel et al.[13] These possible posterior segment complications, among others, make the knowledge of the exact IOP increase induced by surgical procedures such as laser refractive surgery increasingly important.

In our experiment, the IntraLase group had lower IOP increases, although the time needed for the surgical maneuver was almost twice that of the Moria group. It would be interesting to determine which of these factors is more reliable for ocular safety, the time for which the eye is subjected to increased IOP levels or simply the level of the IOP.

There are limitations when using enucleated porcine eyes, because the corneas, although freshly enucleated, were slightly edematous and because the IOP was achieved by an infusion of a glycosylated solution. Clearly, further research is needed in this field.

Real-time IOP can be measured during LASIK with a transducer connected to the anterior chamber. Our results showed a significant increase in IOP during the procedure in both groups, although IntraLase seems to increase the IOP to a significantly lesser extent than does the conventional mechanical microkeratome.

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Ultrasound Biomicroscopic Findings in Rabbit Eyes Undergoing Scleral Suction during Lamellar Refractive Surgery

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Purpose. To evaluate changes of the central anterior chamber depth, cilio-angular cross-sectional surface area, and intraocular pressure in rabbit eyes undergoing application of the scleral suction ring during lamellar refractive surgery.

Methods. Thirty eyes of 30 rabbits were used in the study. The eyes were assigned to one of the following five surgical groups: group 1, no application of the suction ring; group 2, suction for 2 minutes; group 3, suction for 1 minute; group 4, suction for 20 seconds; and group 5, suction for 10 seconds. Ultrasound biomicroscopy (UBM) was performed to determine tomographic features, including central anterior chamber depth, cross-sectional surface area of the ciliary body, and chamber angle structure before and 10 minutes, 1 hour, 2 hours, 1 day, 2 days, 1 week, and 2 weeks after surgery. Intraocular pressure was also measured at each of these time points.

Results. Swelling of the ciliary body occurred in groups 2 to 5 of eyes from 10 minutes up to 1 day after the operation, and its severity was positively related to the duration of suction. Shallowness of the chamber angle was positively related to swelling. All UBM-detectable changes became insignificant compared with baseline values at 2 days after the operation. No significant change was found in the central anterior chamber depth and intraocular pressure during the 2-week postoperative observation period.

Conclusions. Transient change in the ciliary body and the chamber angle occurred frequently after application of the scleral suction ring during lamellar refractive surgery in rabbit eyes. Its severity was positively related to the duration of suction. Swelling of the ciliary body corresponded with the shallowness of the chamber angle without alteration of the corneal-lenticular distance and intraocular pressure. (*Invest Ophthalmol Vis Sci.* 2002;43:3665-3672)

Changes in the ciliary body and angle of the anterior chamber, such as ciliary detachment or angle closure, occasionally occur after surgery for retinal detachment or cataract, pars plana vitrectomy, and filtering surgery. These changes may also occur in eyes of patients who have hypotony, uveitis, concussion injury, or phthisis bulbi.[1-5] However, the likelihood of the occurrence of these changes after lamellar refractive surgery is not well established.

The ciliary body, extending anteriorly from the anterior choroids and peripherally to the iris, is anatomically situated under the covering area of the suction ring used in lamellar refractive surgery. It is reasonable to suspect that transient or permanent damage to the underlying structures may occur after application of the suction ring. In this study, we used ultrasound biomicroscopy (UBM) to perform preoperative and postoperative examinations focusing on central anterior chamber depth (CACD), cross-sectional surface area of the ciliary body (CBCSA), and the chamber angle in rabbit eyes undergoing application of the suction ring with different durations of suction. The purpose of this study was to determine whether the mechanical force exerted by application of the scleral suction ring damages the ciliary body or other associated structures in rabbit eyes and also to evaluate the effects of different durations of suction.

Material and Methods

All experimental procedures were performed in accordance with the ARVO Statement for the Use of Animals in Ophthalmic and Vision Research. Right eyes of 30 adult male New Zealand White rabbits, weighing 3.5 to 4 kg, underwent surgery and were examined. Surgery and examinations were performed with rabbits under general anesthesia with intramuscular injection of 35 mg/kg ketamine HCl and 5 mg/kg xylazine (Rompun; Bayer Sverige AB, Uppsala, Sweden). Thirty eyes were equally divided into five groups with different durations of suction. In group 1, the eyes were mildly proptosed for 2 minutes without application of the suction ring (control group). Suction was performed in group 2 for 2 minutes, group 3 for 1 minute, group 4 for 20 seconds, and group 5 for 10 seconds. After lateral canthotomy was performed, a suction ring of the manual microkeratome (SCMD; United Development Corp., Fountain Hills, AZ) was placed at the sclerocorneal plane of the gently proptosed eye and carefully centered. The suction ring was then firmly applied to the globe. Good adherence to the globe was ensured by observing a small displacement and the slight mydriasis induced by the suction itself. During the suction period, tonometry was performed with a Barraquer tonometer. An intraocular pressure (IOP) of at least 65 mm Hg was confirmed during the whole period of surgery. UBM examinations were made before surgery and at 10 minutes, 1 hour, 2 hours, 1 day, 2 days, 1 week, and 2 weeks after surgery. At each preoperative and postoperative time point, the IOP was measured with a handheld tonometer (TonoPen; Mentor, Norwell, MA).

Ultrasound Biomicroscopy

UBM examinations were performed with a commercial version of the ultrasound biomicroscope (Humphrey Instruments, San Leandro, CA), with a 50-MHz transducer-probe allowing 4- to 5-mm tissue penetration and approximately 50-μm resolution, and a 1.5% hydroxyethylcellulose-filled eye cup. Each eye was examined in its axial section, exploring the transverse diameter passing through the apex of the cornea from the 3-o'clock to the 9-o'clock position (temporal sector) in constant ambient lighting conditions (illumination: 190 lux). Fine move-

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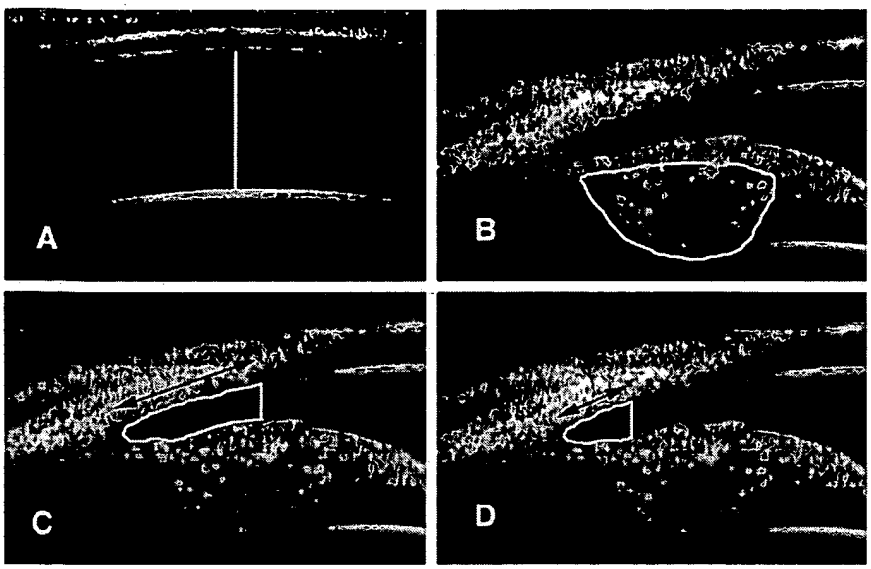

FIGURE 1. Morphologic parameters associated with UBM images, (A) Anterior chamber; *line*: anterior chamber depth. (B) Ciliary process; *line*: outline of the CBCSA. (C) ASA-2000; *line*: outline of the cross-sectional surface area of ASA-2000; *double arrow*: 2000-μm width. (D) ASA-1000; *line*: outline of the cross-sectional surface area of ASA-1000; *double arrow*: 1000-μm width.

ments of the probe were also performed to explore the areas of interest perpendicularly at the temporal area. Images of three areas of interest, including centered on the pupil, the temporal angular region, and the temporal ciliary process, were frozen. Four sets of scans of these areas of interest were obtained. The various anterior segment parameters, described in the following section, were measured on these images with a special caliper issued with the instrument's software package and manipulated by the examiner.

Morphologic Parameters

The definitions of the morphologic parameters assessed were modified from previous studies as follows[6-9]:

1. Central anterior chamber depth (CACD): measured as the central corneal endothelium to the central anterior lens surface (Fig. 1A).
2. Ciliary body cross-sectional surface area (CBCSA): measured as the cross-sectional surface area of the ciliary body with the plane along the longest part of the ciliary process. The ciliary processes were manually selected and isolated (Fig. 1B).
3. Angular surface area 2000 (ASA-2000): the cross-sectional surface area encompassed by the posterior corneal surface, anterior iris surface, and a straight line passing through a point on the posterior corneal surface at 2000 μm from the scleral spur and the point on the anterior iris surface perpendicularly opposite (Fig. 1C).
4. Angular surface area 1000 (ASA-1000): the cross-sectional surface area encompassed by the posterior corneal surface, anterior iris surface, and a straight line passing through a point on the posterior corneal surface at 1000 μm from the scleral spur and the point on the anterior iris surface perpendicularly opposite (Fig. 1D).
5. The presence of ciliary detachment.

In the measurement of parameters 2 to 4, the region of the ciliary body and angular surface area were manually delineated, and quantitative analyses of the images were performed by a single individual blinded to the treatment conditions. With computer planimetry, the border of each image was traced three times, and the automatically measured surface areas were averaged. Measurements of linear parameters were expressed in millimeters and surface area parameters in square millimeters.

Statistical Analysis

In every surgical condition, four sets of UBM images in each eye were scanned, and three calculations were made in each image. The average result of 12 measurements in each eye were calculated. Data are expressed as the mean ± SD. Reproducibility of each eye in each condition was measured by averaging the proportional relationship of the standard deviation of the repeated 12 measures to the mean of those measures. (i.e., coefficient of variation [CV]). Reproducibility of parameters 1 to 4 was measured by average of the CV of the 30 eyes at eight time points. (five groups, each group contains six eyes, each eye had one preoperative and seven postoperative measurements). A CV less than 10% was considered indicative of good reproducibility. The mean of each of the postoperative measurements was compared with the preoperative data, using a paired, two-tailed Student's *t*-test. Pearson's correlation test was used to evaluate the correlation between the change in CBCSA with the change in ASA-2000, ASA-1000, and CACD. $P < 0.05$ was considered to indicate statistical significance.

RESULTS

The CVs of the parameters CACD, CBCSA, ASA-2000, and ASA-1000 were 2.89 ± 0.09, 5.43 ± 0.21, 6.84 ± 0.45, and 7.15 ± 0.52, respectively. The reproducibility of these four parameters was high (CV ≤ 10%).

Figure 2 represents the ciliary body and change in chamber angle surface area after continuous suction for 2 minutes in one rabbit eye in group 2. In these images, we can easily see the increase in CBCSA and decrease in angular surface area 10 minutes and 1 hour after surgery. In the image at 10 minutes after surgery, near total occlusion of the peripheral angle and iridocorneal touch in the midperipheral iris were seen. These changes became less significant 1 day after surgery.

Ciliary Body Cross-sectional Surface Area

Table 1 summarizes the results of preoperative and postoperative CBCSA. There was no significant change in CBCSA in the control group (group 1). The CBCSAs in groups 2 to 5 were increased after surgery at 10 minutes, 1 hour, and 2 hours. The CBCSA decreased 1 day after surgery in all four groups. However, it was still higher than preoperative measurements in all groups. The significance of the postoperative increase in

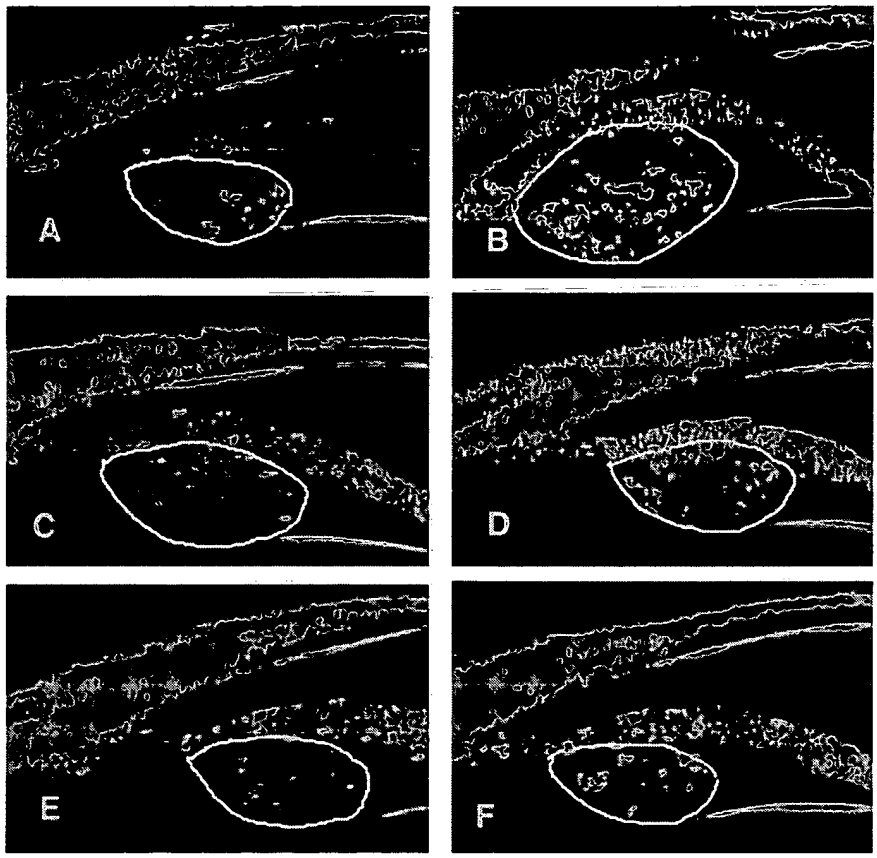

FIGURE 2. UBM image of ciliary body and chamber angle surface area changes in one rabbit eye (eye 2, as shown in Fig. 3) undergoing suction ring application for 2 minutes. (A) Before surgery, (B) 10 minutes after surgery, (C) 1 hour after surgery, (D) 1 day after surgery, (E) 2 days after surgery, and (F) 2 weeks after surgery. *Line*: CBCSA.

CBCSA disappeared 2 days after the operation in all groups. We also noted the positive relationship between the duration of suction and the increase in CBCSA. (Table 1). Group 2 had the largest increase in CBCSA, followed by groups 3 and 4. Group 5 had the smallest increase at each time point. Figure 3 summarizes the time sequence changes in CBCSA in eyes undergoing scleral suction for 2 minutes in group 2.

ASA-2000 and ASA-1000

Table 2 summarizes the changes in ASA-2000 and ASA-1000 in the UBM study. There were no significant changes in ASA-2000 and ASA-1000 in the control group (group 1). There was a significant decrease in ASA-2000 compared with preoperative values in groups 2 to 5 at 10 minutes, 1 hour, and 2 hours after surgery. A decrease was also found in ASA-1000 in groups 2 to 5 at 10 minutes, 1 hour, and 2 hours after surgery. This significance was not found at 2 days after surgery in any surgical group. We also noted the positive relationship between duration of suction and decrease in ASA-2000 and ASA-1000. Group 2 had the largest decrease in ASA-2000 and ASA-1000, followed by groups 3 and 4. Group 5 had the smallest decrease in ASA-2000 and ASA-1000 at each time point. Figure

TABLE 1. Preoperative and Postoperative Ciliary Body Cross-Sectional Surface Area

	Group 1 (Control)		Group 2 (Suction for 2 Minutes)		Group 3 (Suction for 1 Minute)		Group 4 (Suction for 20 Seconds)		Group 5 (Suction for 10 Seconds)	
	Mean ± SD	*P*	Mean ± SD	*P*	Mean ± SD	*P*	Mean ± SD	*P*	Mean ± SD	*P*
Preoperative	1.52 ± 0.09		1.53 ± 0.10		1.60 ± 0.08		1.46 ± 0.10		1.51 ± 0.07	
Postoperative										
10 minutes	1.51 ± 0.05	NS	2.14 ± 0.21	0.007	2.12 ± 0.15	0.013	1.69 ± 0.05	0.019	1.65 ± 0.07	0.047
1 hour	1.49 ± 0.07	NS	2.13 ± 0.16	0.011	1.95 ± 0.18	0.026	1.69 ± 0.05	0.018	1.64 ± 0.03	0.045
2 hours	1.53 ± 0.04	NS	2.07 ± 0.21	0.016	2.01 ± 0.09	0.023	1.72 ± 0.11	0.028	1.54 ± 0.10	NS
1 day	1.50 ± 0.08	NS	1.68 ± 0.09	0.026	1.72 ± 0.13	0.039	1.66 ± 0.13	0.042	1.53 ± 0.06	NS
2 days	1.52 ± 0.11	NS	1.62 ± 0.10	NS	1.68 ± 0.07	NS	1.54 ± 0.11	NS	1.52 ± 0.12	NS
1 week	1.53 ± 0.13	NS	1.61 ± 0.08	NS	1.64 ± 0.11	NS	1.44 ± 0.12	NS	1.50 ± 0.04	NS
2 weeks	1.51 ± 0.06	NS	1.54 ± 0.11	NS	1.57 ± 0.08	NS	1.46 ± 0.10	NS	1.49 ± 0.08	NS

The mean value in square millimeters of each of the postoperative parameters was compared with the preoperative data, by paired, two-tailed Student's *t*-test. $P < 0.05$ was considered to indicate statistical significance. NS, not significant.

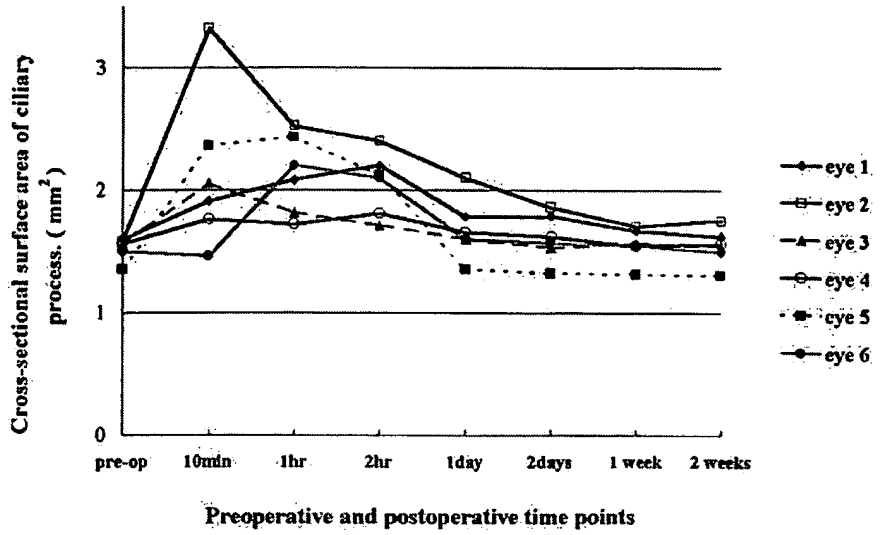

FIGURE 3. Change in CBCSA in six rabbit eyes in group 2 at each postoperative time point, after surgery involving a 2-minute application of the suction ring.

4 summarizes the time sequence changes of ASA-1000 in eyes undergoing scleral suction for 2 minutes in group 2.

Central Anterior Chamber Depth

Table 3 summarizes the CACD measured in the UBM study. The preoperative CACD ranged from 2.29 to 2.38 mm. No significant change in CACD compared with preoperative data was found at any of the postoperative time points in all five groups.

Correlation of the Increase in CBCSA with the Decrease of ASA-2000, ASA-1000, and CACD

The correlation of the increase in CBCSA and the decrease in ASA-2000 was 0.917 ($P < 0.001$), the correlation of the increase in CBCSA and the decrease in ASA-1000 was 0.892 ($P < 0.001$), and the correlation of the increase in CBCSA and CACD was 0.129 ($P = 0.512$).

Presence of Ciliary or Anterior Choroidal Detachment

No ciliary or anterior choroidal detachment was found in any of the experimental rabbit eyes at any time point after surgery.

Changes in IOP

Table 4 summarizes the results of IOP measurements. The preoperative IOP ranged from 9.6 to 12.3 mm Hg. No significant change was found in IOP compared with preoperative data at any of the postoperative time points in all five groups.

TABLE 2. Preoperative and Postoperative ASA-2000 and ASA-1000

	Group 1 (Control)		Group 2 (Suction for 2 minutes)		Group 3 (Suction for 1 minute)		Group 4 (Suction for 20 seconds)		Group 5 (Suction for 10 seconds)	
	Mean ± SD	P	Mean ± SD	P	Mean ± SD	P	Mean ± SD	P	Mean ± SD	P
ASA-2000										
Preoperative	0.70 ± 0.05		0.75 ± 0.02		0.78 ± 0.06		0.69 ± 0.04		0.74 ± 0.04	
Postoperative										
10 minutes	0.71 ± 0.04	NS	0.49 ± 0.08	<0.001	0.55 ± 0.08	0.001	0.56 ± 0.07	0.008	0.61 ± 0.05	0.024
1 hour	0.72 ± 0.13	NS	0.48 ± 0.11	<0.001	0.61 ± 0.09	0.002	0.56 ± 0.07	0.011	0.59 ± 0.13	0.017
2 hours	0.68 ± 0.09	NS	0.56 ± 0.09	0.009	0.65 ± 0.06	0.007	0.62 ± 0.07	0.032	0.57 ± 0.09	0.021
1 day	0.72 ± 0.11	NS	0.68 ± 0.05	0.018	0.71 ± 0.05	0.013	0.63 ± 004	0.034	0.69 ± 0.11	NS
2 days	0.69 ± 0.14	NS	0.72 ± 0.03	NS	0.76 ± 0.06	NS	0.66 ± 0.07	NS	0.68 ± 0.13	NS
1 week	0.71 ± 0.12	NS	0.74 ± 0.02	NS	0.77 ± 0.07	NS	0.67 ± 0.05	NS	0.71 ± 0.12	NS
2 weeks	0.70 ± 0.07	NS	0.75 ± 0.03	NS	0.79 ± 0.06	NS	0.68 ± 003	NS	0.73 ± 0.11	NS
ASA-1000										
Preoperative	0.32 ± 0.05		0.31 ± 0.03		0.33 ± 0.04		0.30 ± 0.02		0.32 ± 0.03	
Postoperative										
10 minutes	0.31 ± 0.04	NS	0.21 ± 0.01	<0.001	0.23 ± 0.02	<0.001	0.22 ± 0.04	0.001	0.25 ± 0.02	0.007
1 hour	0.30 ± 0.09	NS	0.20 ± 0.02	<0.001	0.23 ± 0.02	<0.001	0.24 ± 0.01	0.008	0.26 ± 0.01	0.012
2 hours	0.32 ± 0.06	NS	0.21 ± 0.03	<0.001	0.25 ± 0.03	<0.001	0.24 ± 0.03	0.017	0.27 ± 0.03	0.037
1 day	0.32 ± 0.11	NS	0.27 ± 0.03	0.026	0.31 ± 0.03	0.033	0.25 ± 0.03	0.032	0.30 ± 0.01	NS
2 days	0.31 ± 0.07	NS	0.28 ± 0.04	NS	0.33 ± 0.04	NS	0.26 ± 0.02	NS	0.31 ± 0.05	NS
1 week	0.30 ± 0.08	NS	0.30 ± 0.02	NS	0.32 ± 0.02	NS	0.29 ± 0.03	NS	0.33 ± 0.07	NS
2 weeks	0.32 ± 0.07	NS	0.31 ± 0.03	NS	0.33 ± 0.04	NS	0.30 ± 0.02	NS	0.32 ± 0.06	NS

Data are expressed as in Table 1.

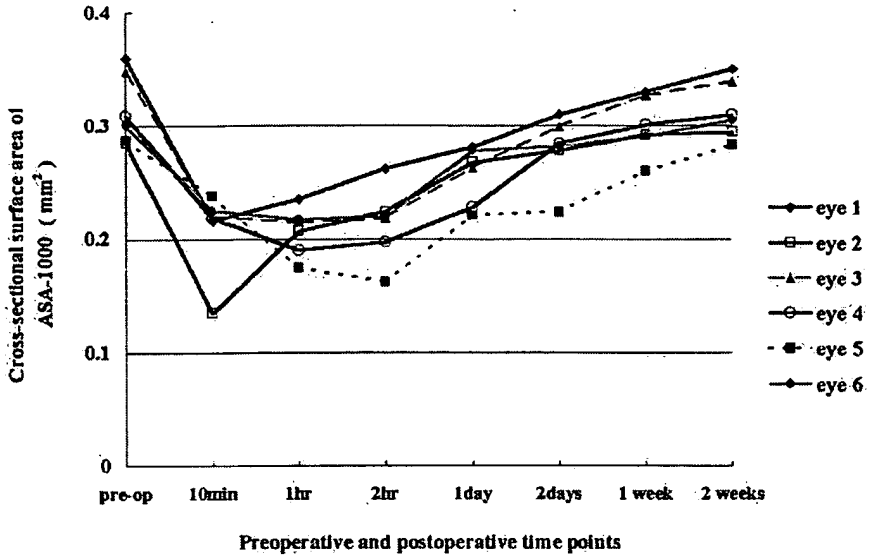

FIGURE 4. Change in ASA-1000 in six rabbit eyes in group 2 at each of the postoperative time points, after surgery involving a 2-minute application of the suction ring.

DISCUSSION

LASIK, one of the various types of lamellar refractive surgery, has gained in popularity worldwide over recent years for the correction of myopia, hyperopia, and astigmatism, because of its excellent surgical results and relatively low complication rate.[10-12] However, some adverse effects, such as flap-related problems, epithelium-associated problems, diffuse lamellar keratitis, and infectious keratitis still occur.[13-17] Suction ring-related complications, such as inadequate suction or total loss of suction, are another potential source of serious problems during LASIK. Other possible suction ring-related complications include retinal vascular occlusion, ischemic optic neuropathy, or macular hemorrhage due to elevation of OP during surgery.[18-20] To perform a perfect lamellar cut with the microkeratome, the IOP must be increased to an adequate level for an adequate duration. Experimental animal studies have found that IOP can increase to between 80 and 230 mm Hg during the vacuuming phase and even greater pressures, from 140 to 360 mm Hg, can occur during the lamellar cut.[21-22] Theoretically, a prolonged high IOP would cause retinal vascular occlusion, especially in patients with vasculopathies or diabetes. Subconjunctival hemorrhage caused by the pneumatic suction ring is another complication mostly without sequelae.[23] It occurs commonly with prolonged suction, excessive eye manipulation, or treatment with platelet-modifying agents such as aspirin or other antiarthritic medications. Another theoretically possible complication is damage to the ciliochoroid and associated structures caused by suction ring-related vacuum pressure. A presumed ciliary body shutdown, with delayed severe hypotony and the presence of nonrhegmatogenous retinal detachment in a patient with keratomileusis was recently reported.[24] However, large series studies on the ciliary body changes after lamellar refractive surgery have not been reported.

Ciliochoroidal changes, such as ciliary body swelling, shallowing of chamber angle or ciliochoroidal detachment have been occasionally noted after intraocular surgery.[1-5] The ciliary body is more susceptible to detachment or other mechanical damage than other parts of the uveal tissue, because no attachment is present between the longitudinal ciliary muscles and the sclera from the scleral spur to the epichoroidal stars in the pars plana.[1] Surgery induced ciliochoroidal detachment is usually temporary and does not cause permanent complications.[1,2,5] However, postoperative thickening of the ciliary

TABLE 3. Preoperative and Postoperative Central Anterior Chamber Depth

	Group 1 (Control)		Group 2 (Suction for 2 Minutes)		Group 3 (Suction for 1 Minute)		Group 4 (Suction for 20 Seconds)		Group 5 (Suction for 10 Seconds)	
	Mean ± SD	P	Mean ± SD	P	Mean ± SD	P	Mean ± SD	P	Mean ± SD	P
Preoperative	2.37 ± 0.01		2.29 ± 0.01		2.31 ± 0.02		2.38 ± 0.03		2.35 ± 0.03	
Postoperative										
10 minutes	2.36 ± 0.02	NS	2.28 ± 0.01	NS	2.31 ± 0.02	NS	2.37 ± 0.02	NS	2.34 ± 0.02	NS
1 hour	2.37 ± 0.01	NS	2.28 ± 0.02	NS	2.30 ± 0.04	NS	2.36 ± 0.03	NS	2.35 ± 0.04	NS
2 hours	2.35 ± 0.01	NS	2.29 ± 0.03	NS	2.31 ± 0.01	NS	2.38 ± 0.01	NS	2.35 ± 0.02	NS
1 day	2.37 ± 0.02	NS	2.30 ± 0.02	NS	2.29 ± 0.03	NS	2.37 ± 0.02	NS	2.36 ± 0.03	NS
2 days	2.38 ± 0.01	NS	2.31 ± 0.02	NS	2.32 ± 0.01	NS	2.36 ± 0.01	NS	2.35 ± 0.01	NS
1 week	2.36 ± 0.04	NS	2.30 ± 0.01	NS	2.31 ± 0.02	NS	2.37 ± 0.05	NS	2.34 ± 0.02	NS
2 weeks	2.38 ± 0.01	NS	2.28 ± 0.03	NS	2.29 ± 0.01	NS	2.39 ± 0.04	NS	2.36 ± 0.03	NS

The mean value in millimeters of each of the postoperative parameters was compared with the preoperative data, by paired, two-tailed Student's *t*-test. $P < 0.05$ was considered to indicate statistical significance. NS, not significant.

TABLE 4. Preoperative and Postoperative IOP

	Group 1 (Control)		Group 2 (Suction for 2 Minutes)		Group 3 (Suction for 1 Minute)		Group 4 (Suction for 20 Seconds)		Group 5 (Suction for 10 Seconds)	
	Mean ± SD	P	Mean ± SD	P	Mean ± SD	P	Mean ± SD	P	Mean ± SD	P
Preoperative	11.37 ± 0.21		12.29 ± 0.11		10.51 ± 0.22		9.68 ± 0.03		12.15 ± 0.23	
Postoperative										
10 minutes	11.16 ± 0.15	NS	12.38 ± 0.41	NS	11.01 ± 0.42	NS	9.77 ± 0.06	NS	11.94 ± 0.32	NS
1 hour	11.87 ± 0.11	NS	12.09 ± 0.02	NS	10.80 ± 0.16	NS	9.76 ± 0.27	NS	12.05 ± 0.14	NS
2 hours	11.95 ± 0.18	NS	12.36 ± 0.13	NS	10.91 ± 0.49	NS	9.97 ± 0.31	NS	11.85 ± 0.62	NS
1 day	12.07 ± 0.22	NS	11.93 ± 0.22	NS	11.10 ± 0.23	NS	10.37 ± 0.22	NS	12.26 ± 0.23	NS
2 days	11.68 ± 0.31	NS	12.31 ± 0.17	NS	10.82 ± 0.51	NS	9.96 ± 0.53	NS	12.05 ± 0.51	NS
1 week	12.06 ± 0.42	NS	12.19 ± 0.41	NS	11.11 ± 0.42	NS	10.27 ± 0.05	NS	11.84 ± 0.72	NS
2 weeks	11.78 ± 0.16	NS	12.08 ± 0.23	NS	10.89 ± 0.21	NS	9.79 ± 0.06	NS	12.06 ± 0.17	NS

The mean value (in mm Hg) of each of the postoperative parameters was compared with the preoperative data, by paired, two-tailed Student's *t*-test. $P < 0.05$ was considered to indicate statistical significance. NS, not significant.

body may rotate the ciliary body anteriorly and cause angle closure.[25] Minamoto et al.[26] described a case of persistent hypotony after an otherwise successful vitreous surgery for epiretinal membrane, in which ciliochoroidal detachment was detected by UBM. Araie et al.[27] also suggested that postoperative ciliary body changes might result in reduction in formation of aqueous humor, which causes development of postoperative hypotony. Because the suction ring used in LASIK is positioned circumferentially from the limbus to approximately 3 mm away from it to the anterior sclera, which covers the anatomic portion of the ciliary body and the anterior choroid, it is reasonable to suspect that the mechanical force and the dramatic changes in IOP during and after use of the suction ring may damage the ciliochoroid and associated tissues.

Clinically apparent choroidal detachment can be checked with a funduscope or echography. However, with the anatomic position of the ciliary body concealed beneath the light-blocking iris and peripheral to the ora serrata, subtle swelling or detachment of the ciliary body remains difficult to evaluate in vivo. The recent development of the high-frequency UBM (Humphrey Instruments) has enabled observation of the chamber angle and ciliary body region at a high resolution that is unparalleled in traditional ophthalmic ultrasonographic instruments.[1,25,26] Methods of measuring the anterior segment parameters have been described. Pavlin et al.[6,7] defined several different anterior segment parameters that have been assessed with the aid of a caliper provided in the computer software accompanying the UBM.[9,28-32] However, due to the more prominent, more convoluted, and larger volume of the ciliary process in rabbit eyes than in human eyes,[33] these parameters are not useful in detecting anterior segment change in rabbit eyes. In this study, we developed a convenient method for measuring anterior segment parameters. The CBCSA and anterior chamber angle at different distances from the scleral spur may provide more convincing information about thickness of the ciliary process or angle opening than traditional one-dimensional measurements.[29,34] However, reproducibility can be a major problem in measuring anterior segment structure with the UBM. When we measure CBCSA, significant variation in cross-sectional area can be expected from plane to plane, depending on whether the plane was oriented along or between the ciliary process. In this study, the measuring plane was oriented along the longest part of the ciliary process determined by one individual who was blinded to the treatment condition. The high reproducibility in our study (CV < 10%) was consistent with the previous study which highlight the high intraobserver reproducibility in measuring UBM images.[35] High reproducibility was shown in the current study, not only of CBCSA, but of CACD, ASA-2000, and ASA-1000.

Ciliary detachment did not occur in any of our studied eyes, even in eyes receiving suction for 2 minutes, which was conceived to be the maximal tolerable suction duration during LASIK.[36] However, swelling of the ciliary body and shallowing of the chamber angle were found in all surgical groups. Longer suction duration led to more severe swelling in the ciliary body, and the swelling correlated positively with shallowing of the chamber angle. In a rabbit eye imaged 10 minutes after surgery involving use of the suction ring for 2 minutes, near total occlusion of the peripheral angle and iridocorneal touch in the midperipheral iris was noted (Fig. 2B). One explanation of these changes was swelling of the ciliary body, although it is also possible that pressure differences between the anterior and posterior chamber during suction may have led to bowing of the iris, which secondarily led to such a manifestation. The mechanism of suction ring-related swelling of the ciliary body is likely to be the uveal congestion from venous obstruction due to high IOP during the procedure, although the position of the scleral ring was not directly over or anterior to the vortex vein, as in case of scleral buckling.[34] It is also possible that local inflammation caused by the surgical procedure or the mechanical outward force exerted on the perilimbal sclera induced the swelling of the underlying ciliary body.

Several studies have reported on the correlation of anterior chamber depth with ciliary body thickness and chamber angle. Gohdo et al.[29] demonstrated that in human eyes with narrow chamber angle, thinning of the ciliary body may be a major factor associated with the anterior location of the lens, increased lens thickness, and decreased anterior chamber depth. Kobayashi et al.[31] showed a strong correlation among anterior chamber depth, trabecular-iris angle, and chamber angle opening in normal infants and children. However, Martinez-Bello et al.[30] showed that trabeculectomy alone widens the angle but does not affect the anterior chamber depth. Our results also showed that narrowing of the chamber angle did not significantly affect the CACD. That there was no change in IOP after surgery in this study is not surprising. The observed changes in ciliary body morphology do not necessarily imply impairment of its function. Also, although narrowed, the chamber angle was always at least partially open. One other less plausible explanation is that a transient decrease in aqueous humor production caused by ciliary body swelling and dysfunction could be compensated by the effect of angle shallowing, which results in partial obstruction of the outflow of aqueous humor and return of IOP.

Except for the possible effects on CACD and IOP, the ciliary body changes may also lead to accommodative impairment. The accommodative apparatus is driven principally by parasympathetic innervation of the ciliary smooth muscle and may cause a reduction in the diameter of the ciliary muscle collar that instigates a series of events leading to an ability to see near objects clearly.[37] In human eyes, the ciliary muscle, which resides in the stroma of the ciliary body, is attached anteriorly to the scleral spur by means of tendons and trabecular meshwork and posteriorly to the elastic network of Bruch's membrane in the choroid. There are no direct connections between the zonules and the ciliary muscle.[38] Therefore, the stroma of the ciliary body is responsible for the transduction of the force of ciliary muscle contraction to the zonules and may influence accommodation.[39] Because the rabbit eye is virtually nonaccommodative, we did not look at changes in accommodation in this study. Although there are no data on accommodation in human or rabbit eyes undergoing scleral suction during lamellar refractive surgery, it is possible that the ciliary body changes shown in our study influenced the function of ciliary muscle contraction, and thus impaired the accommodative ability. This may partially explain the mechanisms of transient accommodative impairment reported by some patients who undergo lamellar refractive surgery. Although a fundamental problem in studying accommodation in the human eye remains that essential structures of the accommodative apparatus are hidden behind the iris and the sclera, UBM has been shown recently to be well suited for in vivo investigations of the zonular apparatus and of accommodation.[40] Further research to determine the impact of swelling of the ciliary body on accommodation after application of the scleral suction ring is needed.

Prolong anesthesia may have influenced our results, especially on day 1. However, there was no significant difference between preoperative and postoperative data at every time point in all measured parameters in the control group, which may rule out the effects of anesthesia. Another point to be clarified is the anatomic differences between rabbit and human eyes. The existence of significant differences of the ciliary body between human and rabbit eyes has been demonstrated with three-dimensional images from very-high-frequency (50 MHz) ultrasound.[33] Compared with human eyes, the rabbit sclera is significantly thinner. The rabbit ciliary body has a small muscular component and very prominent processes. The rabbit ciliary processes are separated by deep valleys with almost vertical sides. Anteriorly, the ciliary processes end abruptly, and approximately every second process leads into an iridial process that runs radially along the posterior surface of the iris. In addition, the rabbit iris is thinner and more delicate than the human iris. The rabbit lens is much larger, and the lens equator attaches directly in one continuous belt at the anterior end of the ciliary processes. In addition, the anterior chamber structures are much shallower in the rabbit than in the human. All these features may accentuate the effect of application of the suction ring in rabbit eyes. Although the anatomy of the rabbit eye differs in many respects from that of the primate eye, rabbit eyes have long been an animal model in the study of glaucoma filtering surgery, retinal surgery, and LASIK.[41-44]

For further confirmation of the findings in this study, the rhesus monkey might provide a more suitable animal model. Although not in human or other primate eyes, this study showed that at least in rabbit eyes, swelling of the ciliary body and shallowing of the chamber angle may be present transiently after scleral suctioning in lamellar refractive surgery. Although all the changes detected by UBM persisted transiently, the possibility of complications due to prolonged suctioning during lamellar refractive surgery are still worthy of concern. Our data suggest that shortening the duration of suctioning during surgery may prevent the development of adverse effects on cilioangular structures. However, caution should be used in direct extrapolation of this rabbit model to the human LASIK procedure. Further long-term and in vivo human studies are needed to confirm the study results.

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Effect of Microkeratome Suction during LASIK on Ocular Structures

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Purpose: To study the effect of microkeratome suction on ocular structures during LASIK.

Design: Observational, prospective case series.

Participants: Twenty-one eyes of 11 patients with myopia or astigmatic myopia (8 females, 3 males) were included. The mean patient age was 36.3 years (median, 37 years; range, 24–48 years), and the mean spherical equivalent was −5.03 diopters (D) (median, −4.63 D; range, −2.38 to −8.38 D).

Methods: We performed preoperative and intraoperative A-scan ultrasonography during application of suction using the Hansatome microkeratome (Bausch & Lomb Surgical, Munich, Germany) to create corneal flaps during LASIK. We also performed preoperative and postoperative B-scan ultrasonography of the posterior ocular segment with special attention to the presence and size of posterior vitreous detachment (PVD).

Main Outcome Measures: We measured changes in the axial length, anterior chamber depth, lens thickness, and vitreous distance (distance from the posterior lens capsule to the posterior pole) during application of the microkeratome suction ring and recorded new occurrences of or increases in the size of the PVD after surgery.

Results: The lens thickness decreased (mean change, −0.20 mm; $P = 0.001$; 95% confidence interval [CI], −0.11 to −0.30) in 18 eyes during application of the suction ring. The vitreous distance increased (mean change, 0.20 mm; $P = 0.004$; 95% CI, 0.08–0.32) in 16 eyes. No statistically significant changes were found in the anterior chamber depth ($P = 0.75$) or axial length ($P = 0.51$). After surgery, 3 of 14 eyes (21.4%) experienced PVD that did not have echographic signs of PVD before surgery. Of 7 eyes with preoperative PVD, the PVD enlarged in 1 eye (14.3%).

Conclusions: During application of microkeratome suction, the lens thickness decreases, whereas the vitreous distance increases, suggesting anterior traction on the posterior segment. The relationship between the observed PVD and LASIK merits further investigation. *Ophthalmology 2005;112:645–649 © 2005 by the American Academy of Ophthalmology.*

LASIK currently is the most commonly performed procedure to treat refractive errors. The range of available correction, the reliability and safety of the results, and the speed of visual recovery after surgery made the procedure a revolutionary breakthrough in ophthalmology in the 1990s.

Technical advances have made the microkeratome cut a safe procedure.[1] A suction ring that is applied around the cornea increases the intraocular pressure (IOP) to more than 60 mmHg, creating a firm cornea and permitting a precise corneal flap to be cut, which is followed by laser ablation.[2,3]

Most reported LASIK complications have been related to the refractive outcome or to corneal and anterior segment injury and wound healing; however, posterior segment complications also occur, although they are less common.[4] Some reports have described an association between LASIK and vitreoretinal pathologic features, such as posterior vitreous detachment (PVD), retinal breaks, retinal detachments, macular holes, lacquer cracks, macular hemorrhages, optic neuropathy, and retinal vein occlusion.[4] Some authors theorize that these adverse effects occur as the result of excimer laser shock waves during corneal ablation, whereas others hypothesize that the suction exerted during the keratome cut causes anteroposterior traction that results in pathologic alterations.[5] However, the effects of LASIK on the posterior segment have not yet been determined precisely.

In this study, we examined the effect of microkeratome suction on the ocular globe, because this is the part of the LASIK procedure that is suspected to have the most relevant impact on the posterior segment structures. We theorized that anteroposterior changes in the ocular globe length, alterations of the anterior segment structures (lens thick-

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ness, anterior chamber depth), or both may occur during microkeratome suction.

Patients and Methods

Study Population, Preoperative Evaluation, and Instrumentation

This prospective, observational case series included 21 eyes of 11 patients (8 females, 3 males) with myopia or astigmatic myopia. The mean patient age was 36.3 years (median, 37 years; range, 24–48 years). The study was performed at the Department of Ophthalmology, Johann Wolfgang Goethe-University, Frankfurt, Germany. Inclusion criteria were suitability for LASIK correction of myopia and absence of ocular pathologic conditions and of relevant systemic diseases.

All participants were evaluated for refractive surgical correction after a thorough ophthalmologic examination, including indirect ophthalmoscopy of the posterior segment and laser interferometry (IOL-Master; Zeiss, Jena, Germany) and were found to be suitable candidates for the LASIK procedure. All subjects were informed about the investigative nature of the ultrasound measurements and they provided informed consent. Because of the noninvasive, observational nature of the study, ethics committee approval was not required.

All patients underwent surgery performed by 1 experienced LASIK surgeon (TK) using the Hansatome microkeratome (Bausch & Lomb Surgical, Munich, Germany) to create a superiorly hinged corneal flap using a 20.3-mm suction ring and 9.5-mm intended flap diameter. The excimer laser ablation was performed with a Technolas C-LASIK 217Z-Laser (Bausch & Lomb Surgical).

A-Scan Ultrasound Biometry

After conventional preoperative preparation and positioning and immediately before applying the microkeratome ring, 3 A-scan ultrasound biometry measurements of the axial length, anterior chamber depth, lens thickness, and vitreous distance (defined as the distance between the posterior lens capsule and the posterior pole) were performed by the surgeon. The microkeratome then was positioned, the suction was initiated, and balanced saline solution drops were administered. After confirming the appropriate position of the microkeratome and ensuring an IOP of more than 60 mmHg using applanation tonometry, the ultrasound A-scan measurements were repeated quickly 3 times. The flap was created, followed by excimer laser ablation and flap repositioning. Of the 3 measurements at each time point, 1 was selected according to the ultrasound pattern and the agreement of the axial length with laser interferometry measurements. Laser interferometry matching was performed in presuction measurements only.

B-Scan Ultrasonography

Immediately before entering the operating room, ocular sonography (B-scan; I^3 System ABD; I^3 Innovative Imaging Inc., Sacramento, CA) was performed by an experienced ocular sonographer with specific attention to the vitreous body and to the prevalence, location, and size of the PVD. The procedure was carried out with patients in the supine position using a standard eyelid contact method without topical anesthesia and with high to maximal gain to detect and localize the ultrasonographic PVD signs, namely, a low-reflection mobile membrane or ring at the vitreous base and partial or complete detachment from the posterior pole. All images were saved electronically for postinterventional comparison. This procedure was repeated in all patients 1 week after surgery to detect vitreoretinal alterations. Because an exact assessment of the changes in the size of the PVD was not possible, the sonographer was asked to consider that progression occurred only when detachment of a new quadrant or involvement of the posterior pole was apparent. Regular postoperative ophthalmologic examinations were performed on days 1 and 7 and 1 month after surgery.

Data Collection and Statistical Analysis

All data were collected and evaluated by the same person (AM) using Microsoft Excel (version 9.0)[6] and SPSS for Windows (version 10.0) programs.[7] P values less than 0.05 were considered statistically significant.

For the A-scan measurements, the mathematical differences between the intraoperative and preoperative values were calculated for the anterior chamber depth, lens thickness, axial length, and vitreous distance. Besides the descriptive statistics, the Wilcoxon matched pairs test was performed to detect statistical significance.

In the B-scan studies, the number and percentage of new PVDs and increases in preoperatively observed PVDs were assessed. In a subgroup without preoperative echographic PVD signs, the incidence of PVD was compared with that in a subsequent age- and refraction-matched group that did not undergo intraoperative A-scan measurement and therefore had a shorter suction time.

Results

The mean spherical equivalent was −5.03 diopters (D; median, −4.63 D; range, −2.38 to −8.38 D), and the mean axial length (IOL-Master) was 25.08 mm (median, 25.06 mm; range, 24.18–26.79 mm). Table 1 shows the patient data.

A-Scan Ultrasound Biometry

The lens thickness decreased during application of microkeratome suction in 18 eyes (85.7%; mean decrease, −0.20±0.21 mm; P = 0.001; median decrease, −0.2 mm; range, +0.27 to −0.72 mm; 95% confidence interval [CI], −0.11 to −0.3 mm). The vitreous distance increased in 16 eyes (76.2%; mean increase, 0.20±0.26 mm; P = 0.004; median increase, −0.19 mm; range, +0.77 to −0.2 mm; 95% CI, 0.08–0.32 mm). There were no statistically significant changes in the axial length (mean change, −0.01 mm; P = 0.51) or the anterior chamber depth (mean change, −0.01 mm; P = 0.75; Table 1). A post hoc power calculation of nonsignificant parameters (axial length and anterior chamber depth) revealed a power of 0.0943 and 0.0499, respectively. Proposing a desired power of 0.90, the required sample size for statistical proof of the observed difference is calculated at n = 505 for the axial length and n = 2136 for the anterior chamber depth. Therefore, the study was not adequately powered to detect a difference in their measures if there was a difference of 0.01 mm.

B-Scan Ultrasonography

Before surgery, 14 of 21 eyes (66.7%) had no echographic signs of PVD. The remaining 7 eyes (33.3%) had partial PVD, detected by ultrasound, of which 1 eye had an enlarged PVD (14.3%). The PVD in the temporal and inferior quadrants before surgery extended toward the central region, including the posterior pole. After surgery, 3 of 14 eyes without preoperative echographic signs of a PVD experienced a partial PVD (2 patients; 21.4%; 95% CI, 4.7–50.8; Table 1). In an age- and refraction-matched group that

Table 1. Difference between Intraoperative and Preoperative A-Scan Ultrasound Measurements and B-Scan Examinations*

Patient No.	Age (yrs)	Gender	Eye	Spherical Equivalent (D)	Axial Length/ Laser Interferometry	Axial Length Difference (mm)	Anterior Chamber Depth Difference (mm)	Lens Thickness Difference (mm)	Vitreous Distance† Difference (mm)	Preoperative B Scan Results	Postoperative B Scan Results
1	48	M	L	−2.38	24.47	0.02	0.19	−0.36	0.19	No PVD	No change
2	36	F	R	−3.00	24.56	−0.16	−0.19	−0.21	0.24	No PVD	No change
3	38	F	R	−3.25	24.48	−0.10	0.15	−0.15	−0.1	PVD nasal	No change
4	38	M	R	−3.38	25.06	0.46	0.00	−0.31	0.77	No PVD	No change
5	36	F	L	−3.50	24.79	−0.07	−0.05	−0.11	0.09	No PVD	No change
6	38	F	L	−3.63	24.47	0.29	0.72	−0.72	0.29	PVD nasal	No change
7	48	M	R	−3.75	25.30	0.22	0.10	−0.46	0.58	No PVD	No change
8	36	F	L	−4.38	24.18	0.09	−0.19	−0.05	0.33	No PVD	No change
9	42	F	L	−4.50	25.11	−0.21	0.10	−0.31	0.0	PVD	No change
10	42	F	R	−4.50	25.16	0.08	0.38	−0.10	−0.2	PVD	No change
11	28	F	L	−4.63	24.78	−0.11	0.19	−0.20	−0.1	No PVD	PVD inf.
12	28	F	R	−4.63	24.97	−0.08	0.19	−0.31	0.04	No PVD	PVD inferior/ nasal inferior
13	38	M	L	−4.75	25.64	−0.26	−0.05	−0.26	0.05	No PVD	No change
14	36	F	R	−5.25	24.48	−0.00	0.09	0.05	−0.14	PVD temporal/ superior	No change
15	39	F	L	−5.50	25.20	−0.16	−0.05	−0.25	0.14	No PVD	No change
16	39	F	R	−5.88	25.58	−0.05	−0.19	−0.10	0.24	No PVD	PVD superior
17	24	F	R	−7.13	24.82	0.14	−0.24	−0.15	0.53	No PVD	No change
18	24	F	L	−7.63	25.15	0.11	−0.77	0.26	0.62	No PVD	No change
19	34	M	R	−7.63	25.86	−0.15	−0.39	−0.05	0.29	PVD temporal	No change
20	34	M	L	−8.00	25.89	−0.11	−0.20	0.00	0.09	No PVD	No change
21	37	F	L	−8.38	26.79	−0.17	−0.05	−0.46	0.34	PVD temporal/ inferior	PVD temporal/ inferior/central

F = female; L = left; M = male; PVD = posterior vitreous detachment; R = right.
*Data sorted by spherical equivalent.
†Distance from the posterior lens capsule to the posterior pole.

had no preoperative echographic PVD signs and that did not undergo intraoperative A-scan measurement (shorter suction time), we observed 1 case of new PVD. However, the difference between both groups was not statistically significant.

Discussion

The high number of refractive surgical procedures performed, with LASIK being the most popular, has led to an increasing awareness of its side effects and potential complications. Posterior segment complications resulting from LASIK have been reported in rare cases.[4] Large studies have shown no greater incidence of retinal detachment after LASIK compared with the reported incidence of retinal detachment in patients with myopia who have not undergone refractive surgery.[4,8,9] However, a number of reports have been published on posterior segment complications directly associated with LASIK.[4] Several pathogenetic theories have been postulated, of which the potential changes in the shape of the ocular globe caused by application of the microkeratome seems to be the most contributory.[5] The application of the suction ring and the rapid increase in IOP, which is necessary to stabilize the anterior segment just before flap creation, may lead to a change in the shape of the anterior segment, displacement of the lens, compression and decompression of the posterior segment structures by conduction of power via the vitreous body or sclera, or all of these. Possible results are anteroposterior traction or compression potentially leading to posterior segment complications—for example, retinal tears. None of these theories has been assessed in a study, and the effects of LASIK on the posterior segment are not known with certainty.

In the present study, we quantified the effect of microkeratome suction on the ocular globe structures in vivo. The consistent decrease in lens thickness and increase of vitreous distance (posterior lens capsule to retina) that we observed underscore the power of the microkeratome to affect the ocular architecture. The decrease in lens thickness is comparable with displacement of the lens in the anterior direction along with the anterior hyaloid. This may accelerate vitreous detachment and cause traction at the vitreous base, the posterior pole, or both, where the junction between the vitreous body and the retina is tight. This phenomenon may explain the retinal breaks, retinal detachments, macular hemorrhages, and lacquer cracks reported by others and the PVDs that we observed.

Luna et al[10] reported the development of PVD after LASIK with an incidence of 2% in a group of 50 patients with low myopia (−1.25 to −3.5 D) and 24% in a group of 50 patients with high myopia (−6 to −10 D). Considering the data from the 100 eyes, this corresponds to 13%; thus, there is not a great deal of difference between our results and the data in the literature. No definitive answer was found, however, regarding the incidence and risk factors associated with this phenomenon, because the number of

eyes in the present study was too small to determine exact incidence rates (see 95% CIs). Furthermore, we should consider that closed lids may lessen the sensitivity of B-scan sonography in detecting PVD; thus, some changes might not have been detected. Performing intraoperative A-scan measurements requires longer suction periods than in routine LASIK procedures, which may result in an increased risk of PVD. A comparison with an age- and refraction-matched group without intraoperative A-scan measurement did not reveal a statistically significant difference. However, this is, most probably, the result of the small sample size in our study. Thus, our B-scan results need to be verified by future studies with a larger number of cases. Nevertheless, we recommend adding the development of PVD to the informed consent form and to advise patients, particularly those with higher myopia, about the nature, symptoms, and consequences of PVD.

Mostafavi et al,[11] who reported the preliminary results of A-scan measurement from 6 cadaver porcine eyes during application of microkeratome suction, observed a mean shortening of the ocular globe of 0.67 mm. In contrast, Flaxel et al[12] observed an increase in axial length and no change in the anterior chamber depth after application of the suction ring in 8 human eyes from an eye bank. Neither finding was confirmed in our study in vivo, because no statistically significant change in the axial length was found. The axial length measurements in cadaver eyes outside the orbital cavity, as performed by both above-mentioned study groups, may differ from those performed in vivo and therefore may provide less relevant data. However, our results corroborate the hypothesis of Flaxel et al regarding the presence of anterior traction caused by displacement of the vitreous body during suction but not caused by ocular globe elongation.

Our study did not reveal a statistically significant alteration in the anterior chamber depth. This finding is important, as is the observation that the axial length was insignificantly altered. Any systematic mistake, such as tilting of the ultrasound probe during intraoperative measurements, would result in systematically different axial length and anterior chamber depth measurements. The increase in the vitreous distance is a result of a decrease in the lens thickness, when considering that the axial length and the anterior chamber depth remained unchanged.

Based on the available data, the mechanics of microkeratome-induced alterations in ocular structures can be described as follows. Application of the suction ring beneath the limbus leads to circular traction on the sclera, the adjacent ciliary body, and the zonula ciliaris, resulting in traction on the equatorial region of the lens, which by itself causes a decrease in lens thickness (the opposite effect of accommodation). In young patients, usually less than 40 years of age, the posterior capsule of the lens strongly adheres to the anterior hyaloid. The decrease in lens thickness, similar to the displacement of the lens anteriorly, is accompanied by a forward movement of the anterior hyaloid, causing traction at the vitreous base, the posterior pole, or both. This theory also explains how vitreoretinal traction is generated by a change in the lens architecture without substantial lengthening of the eye. In fact, many of the reported posterior segment complications of LASIK may be related to the traction on the vitreous body and the consequent conduction of the power vector to the retina. The development of PVD, as seen in our study, supports the hypothesis that there must have been some traction applied to the posterior segment.

The mean changes in lens thickness and vitreous distance (0.2 mm) appear too small to cause vitreoretinal alterations. However, the range of up to −0.72 mm for the lens and +0.77 mm for the vitreous body highlights the relatively high interindividual deviations. Furthermore, this effect may be much higher when suction is initiated and released after the flap is created. In fact, the rarity of vitreoretinal complications associated with LASIK[4,8] makes clear that the power that causes them must be low and harmless for normal vitreoretinal consistency. Certain predisposing factors are necessary for the occurrence of complications that are caused by a mild amplitude of traction.

In this study, the A-scan measurements were performed with direct contact between the probe and the cornea without a water funnel (no immersion technique). The direct contact with the corneal surface has the potential danger of depressing the cornea, thereby resulting in smaller inaccurate measurements of the anterior chamber depths and axial lengths. This is of special interest when considering that during microkeratome-induced suction, the cornea becomes firmer and deformation of the anterior chamber by the probe is less likely than during the preoperative normal tension A-scan assessment.

An important step in flap creation is cutting through the cornea. This occurs during the suction period. During this phase, the cornea and the anterior chamber are subject to pressure from the microkeratome. As a consequence, the IOP rises even more and the ocular structures may be affected during flap creation in ways not experienced during the suction period before flap creation. We did not study the alterations caused by this specific part of the microkeratome application. The effect of excimer laser waves on the posterior segment seems to be low, as shown by Krueger et al.[13] Although the vitreoretinal complications of LASIK are most likely related to the mechanics of microkeratome application, a contributory effect of the excimer laser shockwave cannot be ruled out.

The mechanics of microkeratome suction can be compared to that of blunt ocular trauma when the ocular globe is compressed and quickly released.[14,15] The range of LASIK-related posterior segment complications is similar to that of blunt ocular trauma, however, at a much lower level incidence and degree.

Major limiting factors of our study were the static nature of A-scan ultrasound biometry, which delivers information at a very specific moment, namely, as the suction is applied, and the limited number of eyes for the determination of the exact incidence and risk factors for the occurrence of PVD (B-scan assessment). A dynamic online evaluation of the axial length and lens thickness would deliver interesting data at the time of suction initiation and release. Furthermore, we included only myopic eyes in this study, and the ocular changes in hyperopic eyes may be different.

Further examination of microkeratome mechanics and the effect on the ocular structures is necessary to understand

thoroughly the impact of LASIK on the posterior segment of the eye.

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Proposed Mechanism for Retinal Tears after LASIK

An Experimental Model

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Objective: To demonstrate axial length changes associated with anterior shift of the lens/iris diaphragm and anterior vitreous base in human cadaver eyes during suction ring application preceding Moria LASIK, and to propose that these changes may be associated with anterior retinal tears.

Design: Human eye study.

Materials: Eight human eye bank eyes ranging in age from 65 to 73 years. Two eyes had a history of intraocular surgery involving cataract extraction and intraocular lens implantation.

Intervention: Measurements of intraocular pressure via internal manometer and Tono-Pen, anterior chamber depth, and axial length before and after application of a Moria LASIK suction ring.

Main Outcome Measures: Change in anterior chamber depth and axial length after Moria LASIK suction ring application.

Results: Axial length increases (mean change = 1.125 mm, $P = 0.02$) after application of the suction ring, whereas anterior chamber depth shows no significant difference (mean change = −0.01 mm, $P = 0.98$), suggesting anterior movement of the vitreous base resulting in traction on the anterior retina.

Conclusion: Axial length increase with anterior displacement of the vitreous base during suction ring placement might predispose susceptible eyes to anterior retinal tears during and after LASIK. *Ophthalmology 2004;111:24–27 © 2004 by the American Academy of Ophthalmology.*

Laser in situ keratomileusis for the correction of various levels of myopia has become increasingly popular over the past 6 years. It is becoming more useful for the correction of moderate to high myopia, and is being used with increasing frequency to correct even highly myopic eyes. The anterior segment complications have been well documented and reported in the literature.[1,2] As the use of LASIK has become more common, there have been several reports proposing a relationship between LASIK and retinal detachments in these myopic eyes.[3–6]

We developed a model utilizing human eye bank eyes to demonstrate changes in the axial length of the eye during application of the Moria (Paris, France) LASIK suction ring, and propose a mechanism for the development of retinal tears in susceptible myopic eyes.

Patients and Methods

In this experimental model using human eye bank eyes, we prospectively evaluated changes in several parameters before, during, and after the application of a Moria LASIK suction ring.

Before placement of the suction ring, intraocular pressure (IOP) was measured using a manometer manufactured by Precision Dynamics (San Fernando, CA) (Fig 1). This device was left in place for the duration of the measurements. Intraocular pressure was also measured before and after suction ring placement via a Tono-Pen XL handheld tonometer (Mentor, Norwell, MA). Anterior chamber depth and axial length measurements were monitored before and after suction ring placement with a Humphrey Ultrasonic Biometer manufactured by Humphrey Instruments Inc. (San Leandro, CA).

Measurements were recorded from 8 consecutive human eye bank eyes ranging in age from 65 to 73 years obtained from the Loma Linda University Medical Center Eye Bank (Table 1). Two eyes had a history of intraocular surgery, consisting of cataract

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The authors have no proprietary interest in any of the instruments or procedures used in this project.

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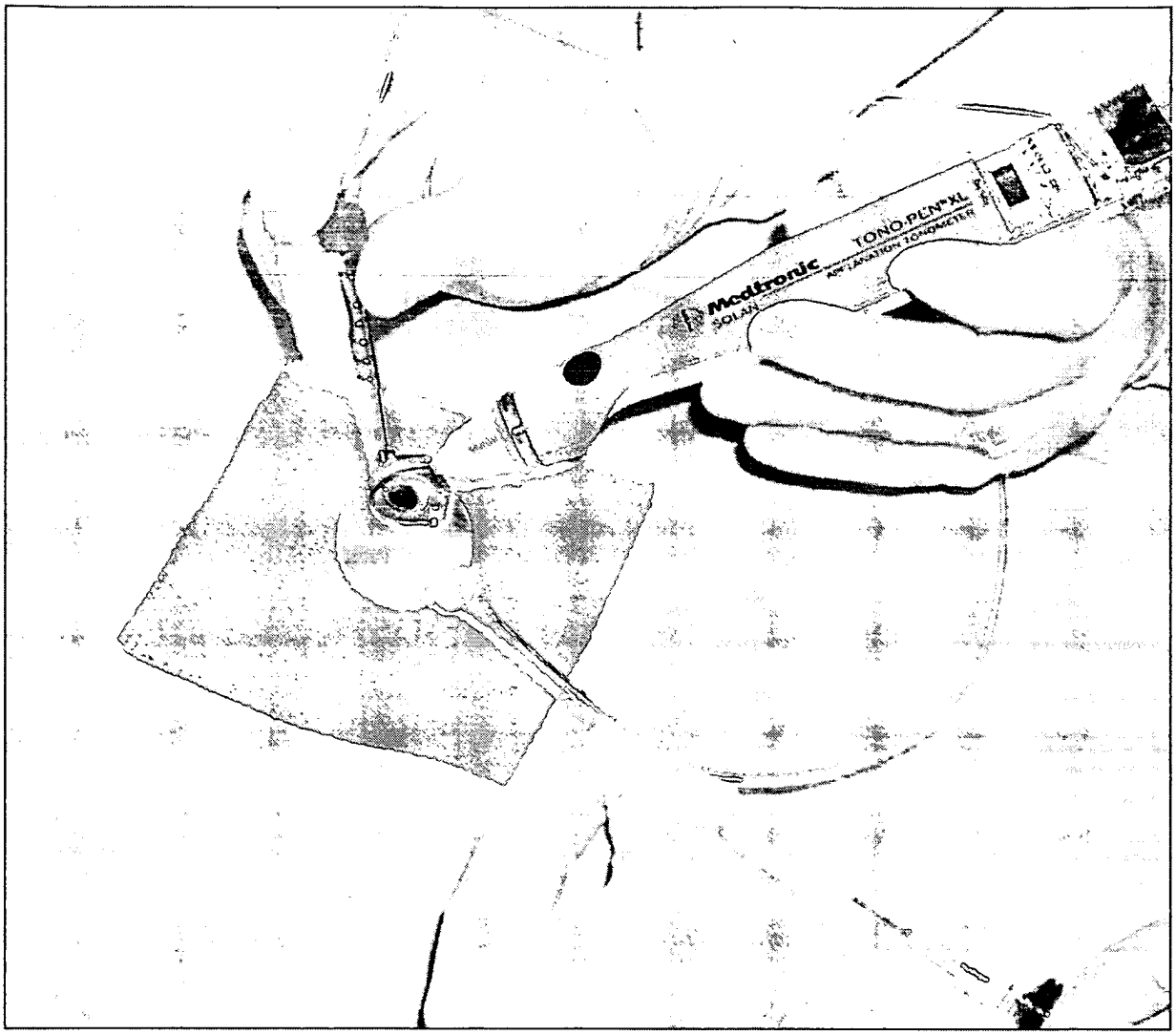

Figure 1. Tono-Pen intraocular pressure measurements with suction ring and intraocular manometer in place. This image was manipulated with 3-dimensional animation to help demonstrate the procedure.

extraction with intraocular lens implantation at least 1 year before enucleation. No eyes had a history of ocular trauma. The number of days after removal ranged from 2 to 14 days, and all eyes were kept in moist chambers, unpreserved, until the experiments were carried out on a single day.

Results

Results are summarized in Table 1. Axial length measurements increased (mean change = 1.125 mm, $P = 0.02$) after application of the suction ring, whereas anterior chamber depth showed no significant difference (mean change = −0.01 mm, $P = 0.98$) before and after suction ring placement (Fig 2). The Humphrey Ultrasonic Biometer was not able to monitor the anterior chamber depth for human eye bank eyes 03-0515 and 03-052, both having the status post–cataract surgery, though it was accurately able to monitor the axial length measurements. The postsuction anterior chamber depth reading on eye 04-028 was not available, due to a technical difficulty. These values were not included in the final statistical analysis (Table 1).

Intraocular pressure increases ranged from 30 to 50 mmHg after suction ring placement (mean change = 40.9 mmHg, $P<0.0001$). These IOP rises have been previously documented.[7,8] There was a difference noted between the direct measurements as made by the intraocular method (manometer) and the external method (Tono-Pen) after application of the suction ring, with higher measurements demonstrated by the Tono-Pen method.

Discussion

Refractive surgery for the correction of ametropia, especially myopia, is well established, but these procedures may

Table 1. Changes in Intraocular Pressure (IOP), Axial Length, and Anterior Chamber (AC) Depth before and after Moria LASIK Suction

Eye ID #	Change in IOP (mmHg)	Baseline Axial Length (mm)	Postsuction Axial Length (mm)	Baseline AC Depth (mm)	Postsuction AC Depth (mm)
04-0130	30	23.34	25.83	2.73	2.20
04-0140	42	21.97	23.31	4.60	3.80
04-0270	45	22.00	21.80	2.46	3.73
04-0280	38	22.64	21.83	4.53	NA
03-0515	50	22.73	24.26	NA	NA
03-0520	40	22.53	24.13	NA	NA
04-0152	42	22.29	24.15	2.86	2.60
04-0162	40	22.79	23.98	2.06	2.33

NA = not available.
Mean change in IOP = 40.9 mmHg (standard deviation [SD] = 5.7), $P<0.0001$.
Mean change in axial length = 1.125 mm (SD = 1.092), $P = 0.02$.
Mean change in AC depth = −0.01 mm (SD = 0.82), $P = 0.98$.
Statistical tests were calculated using the paired t test; $P<0.05$ is statistically significant.

lead to complications. Ongoing discussion in the literature since the advent of refractive surgery has shown concern with the possibility of retinal tears and detachments after refractive surgical procedures, though these cases may represent the normal increased incidence of retinal complications in the myopic eye.[6,9–12] Laser in situ keratomileusis has been the refractive procedure of choice for the correction of moderate to high degrees of myopia. Many clinical studies have demonstrated the efficacy and predictability of this procedure with a low complication rate, with most of the complications related directly to the procedure itself and involving primarily the anterior segment of the eye.[1,2,13,14]

There have been recent reports of associations between LASIK and posterior segment pathology, leading to an increased interest in the potential causal relationship between LASIK and posterior segment pathology.[6,15–20] We undertook an experimental study in an attempt to demonstrate physical changes occurring within the eye that could explain the development of post-LASIK retinal pathology.

The exact mechanism used for performing LASIK involves an excimer laser and a microkeratome that has a pneumatic suction ring. The suction ring is a circular chamber that fixates the eye by means of a vacuum. The underside of the fixation ring has a vacuum chamber that seals against the globe. According to the manufacturer, the IOP must exceed 65 mmHg to obtain a resection that is uniform, regular, and of the appropriate diameter. Ozdamar and colleagues have proposed and shown that the shock wave generated by the impact of the excimer energy on the cornea can generate a pressure of up to 100 atmospheres, resulting in mechanical stress on the eye.[5,21] Several studies have looked at the basic science of the pressure waves within the eye.[22,23] These authors propose a potential for shock waves generated in the anterior segment to affect structures in the posterior segment, as has also been proposed by Charteris and colleagues.[3–6,22,23]

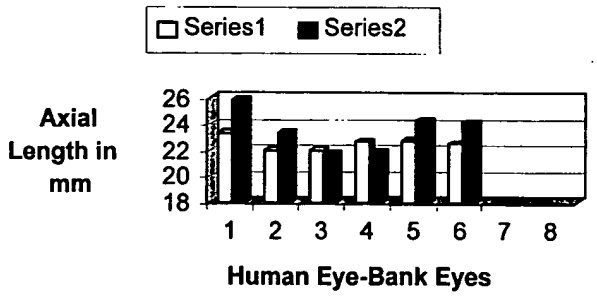

Figure 2. Changes in axial length before (series 1) and after (series 2) Moria LASIK suction ring.

Other factors besides the degree of myopia may also play a role in the incidence of posterior segment pathology. Some are the difference in the design of each microkeratome as well as different rates of vacuum rise and different maximum vacuum levels between microkeratomes. Other variables, such as photoablation spot size and rate of pressure release by the microkeratome, may also be important.

In the present study, we demonstrate the actual increase in axial length measurements after the placement of the suction ring without change in the anterior chamber depth, utilizing an A-scan ultrasound unit. This would indicate that the elongation of the eye is primarily due to a change in the dimensions of the vitreous cavity, rather than a change in the depth of the anterior chamber. A similar mechanism has recently been proposed by Arevalo and colleagues in an editorial in *Ophthalmology*.[6] These changes in the dimensions of the eye could induce a posterior vitreous detachment (PVD) as well as place traction on areas of lattice degeneration located in the anterior retina. Careful follow-up in these cases is warranted, as retinal tears and detachments can occur up to 6 months or even longer after the initial event.[24–27]

Further studies are underway comparing preoperative and postoperative incidences of PVDs in eyes undergoing LASIK. El-Agha and coauthors reported their preliminary unpublished data at the 2001 Vitreous Society meeting; they found a 10% incidence of PVD in moderate myopes (2.25 to −5.75 diopters [D]) and an even greater incidence of PVD in high myopes (−7.50 to −11.00 D) after LASIK.

We have proposed a mechanism by which LASIK may precipitate the development of a retinal tear or detachment in susceptible myopic eyes. We feel that although retinal detachment after LASIK may be uncommon and no cause–effect relationship between LASIK and retinal detachment has been proven, the possibility exists, based on the findings of the present study that LASIK has the potential to aggravate pre-existing retinal pathology and precipitate an acute PVD or retinal tear in areas of pre-existing retinal pathology. It may be beneficial for at-risk eyes of highly myopic patients scheduled for LASIK to have a careful dilated retinal examination with scleral depression to identify high-risk lesions, especially if these patients relate any symptoms of vitreous syneresis. These patients should receive preoperative counseling regarding the risk of retinal problems with or without the LASIK procedure. It is not clear at this time which eyes, if any, would benefit from prophylactic

treatment for retinal pathology, and further research is needed into this topic. Definitely, patients with eyes with subclinical retinal detachments should be discouraged from proceeding with LASIK, whereas patients with eyes with only lattice degeneration and no retinal holes, or only atrophic holes, may need only counseling and no pre-LASIK treatment. These patients should be made aware that LASIK corrects only the refractive component of myopia, and that myopic eyes have the anatomical potential for serious complications with or without undergoing the LASIK procedure.

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CLINICAL AND EXPERIMENTAL
OPTOMETRY

ORIGINAL PAPER

Dry eye after LASIK: Comparison of outcomes for Asian and Caucasian eyes

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Background: Dry eye is a common complication of LASIK surgery. Our clinical impression was that post-LASIK dry eye was more problematic for our Asian patients. The aim of this study was to determine if dry eye after LASIK is more prevalent, more sustained and more severe in Asian eyes compared with Caucasian eyes.

Methods: This study was based on a retrospective analysis of a clinical database. Data (n = 932 eyes, 932 patients) was collected before and after (week 2 and months 1, 3 and 6) LASIK surgery. Patients were defined as Asian if both parents were of East Asian ethic origin. Assessments included dry eye symptoms, ocular surface staining, tear volume, tear secretion, tear film stability and corneal sensation.

Results: Asian eyes had greater ocular surface staining, poorer tear film stability and lower tear volume before LASIK and at all times after LASIK. Dry eye symptoms occurring 'often or constantly' were more prevalent at all time points after LASIK in Asian eyes. Chronic dry eye persisting six months or more after LASIK was diagnosed in 28 per cent of Asian eyes and 5 per cent of Caucasian eyes ($p < 0.001$). Asian patients with chronic dry eye were predominantly female, reported dry eye symptoms, had greater ocular surface staining and lower tear secretion, stability and volume before surgery. After LASIK, Asian eyes had a slower return to pre-operative values for ocular surface staining, tear volume and corneal sensation.

Discussion: The risk of chronic dry eye after LASIK was significantly higher in Asian eyes. Contributing factors could include racial differences in eyelid and orbital anatomy, tear film parameters and blinking dynamics and higher attempted refractive corrections in Asian eyes.

Key words: Asian eye, dry eye, LASIK, myopia

Dry eye preventing safe and comfortable contact lens wear is a major motivating factor for patients considering refractive surgery.[1] Dry eye is considered by refractive surgeons to be the most common complication of LASIK surgery.[2] Cutting a LASIK flap and performing a stromal ablation disrupts the corneal innervation and produces a relative loss of corneal sensation for up to six months after surgery.[3-6] This loss of corneal sensation appears to be a significant contributing factor to the reduction in tear secretion, tear film stability, tear clearance, blink rate, conjunctival goblet cell density and the increase in tear osmolarity and punctate epitheliopathy of the post LASIK eye.[4,6-11] In patients with dry eye before LASIK,[11] in long-term contact lenses wearers[4,9] and in those having deeper surgical ablations[5] and superior hinged flaps,[6] the return of corneal sensation to levels observed before surgery appears to take longer than six months and is associated with more persistent dry eye signs and symptoms.[4,6,9]

Recent studies[12-14] have suggested that dry eye is more prevalent in Asian

populations than in Caucasians. Clinically, we had formed the impression that sustained dry eye after LASIK was more common in our Asian patients. This observation was of concern to us as the prevalence of myopia is much higher in Asians than in Caucasians[15,16] and appears to be increasing in urbanised Asian communities.[17] LASIK continues to be the dominant refractive surgery procedure for myopia,[18] therefore it is likely that increasing numbers of myopic Asians will seek refractive surgery. In this study, we analysed our clinical patient database to compare Asian and Caucasian patients after LASIK. The aims of the analysis were to determine if dry eye after LASIK is more prevalent, more severe and more sustained in Asian eyes.

METHODS

The study was a retrospective analysis of 932 patients who underwent LASIK for correction of myopia and myopic astigmatism at Excimer Laser Vision Centre, Brisbane, Australia, between August 1998 and December 2002. Our database tracks surgical outcomes for all myopic LASIK procedures and contained a total of 1,886 LASIK procedures, of which 1,846 were primary LASIK procedures on 1,026 patients. Of these, 932 patients met the inclusion criteria and had complete data for at least one eye for 12 months. Data analysis was based on these 932 patients. In patients who had surgery on both eyes, only the right eye data were analysed, provided the data were complete and the inclusion criteria were met. All patients received a detailed explanation of the procedures involved in the study and provided written informed consent. The Queensland University of Technology Human Research Ethics Committee provided written approval of the study protocol.

The eligibility criteria used in the study were:

- no autoimmune disease, metabolic disease or uncontrolled systemic disease
- no active disease of the external eye or adnexae
- no intraocular disease
- no degenerative or neurotrophic corneal disease
- no pre-operative or post-operative use of topical medications other than those prescribed
- no previous ocular surgery or trauma
- not pregnant or breastfeeding
- stable refraction for at least 12 months prior to LASIK
- stable keratometry and pachymetry following cessation of contact lens wear
- no lenticular opacities identified before or after surgery that were deemed to have a significant effect on the refractive outcome
- compliance with prescribed tear film and ocular surface management before and after surgery.

Patients were defined as Asian if one or both parents were of East Asian ethic origin (for example, Chinese, Japanese, Thai, Filippino, Vietnamese, Korean, Taiwanese, Singaporean, Malaysian). To avoid complicating the analysis, we excluded patients who had partial Asian ancestry. We also excluded patients of Indian Asian ancestry.

Pretreatment of the tear film and ocular surface was performed on indication where specific tear film and ocular surface problems were identified before LASIK. Pre-treatment measures included:

1. Non-preserved artificial tears, gels or ointments; non-preserved steroid (prednisolone sodium phosphate 0.5 per cent or 1 per cent hydrocortisone ointment) for ocular surface inflammation and/or eyelid margin inflammation.
2. Silicone punctal plugs (Flexplug, Eagle Vision, Memphis USA) for tear deficiency, where artificial lubricants alone were insufficient.
3. Lid hygiene procedures for eyelid disease.

All LASIK procedures were performed by one experienced LASIK surgeon (LL) using a surgeon-adjusted ablation nomogram. The lamellar flaps were created using the automatic corneal shaper (Chiron Vision, Irvine, USA) and the excimer laser (Nidek EC-5000, Nidek, Gamagori, Japan) performed the stromal ablations. The flaps were 8.5 mm wide and 130 µm thick with an optic zone of 5.5 to 6.5 mm and a transition zone of 7.5 mm. After surgery, all eyes received a standard treatment of non-preserved chloramphenicol 0.5 per cent (Chauvin Pharmaceuticals, Essex, UK) four times per day for three days and fluorometholone acetate 0.1 per cent (Flucon, Alcon Laboratories, Fort Worth USA) four times per day, tapering one drop per week over one month. All patients were instructed to use non-preserved artificial tears (Cellufresh [sodium carboxymethylcellulose 0.5 per cent in lactate buffer, non-preserved, Allergan, Irvine USA] and/or Bion Tears [hydroxypropyl methylcellulose 0.3 per cent, Dextran 70 0.1 per cent in bicarbonate buffer, Alcon Laboratories, Fort Worth USA]) at least every two hours for the first month after surgery and then at least four times per day for the 12 months after surgery.

Patients were also instructed to use sodium carboxymethylcellulose 1.0 per cent in lactate buffer, non-preserved (Celluvisc, Allergan, Irvine USA) for at least one week after LASIK as a night-time lubricant and, if long-term night-time lubrication was required, then Celluvisc or carbomer gel, non-preserved (Polygel, Alcon Laboratories, Fort Worth USA) or paraffin plus lanolin, non-preserved ointment (Polyvisc, Alcon Laboratories, Fort Worth USA) were prescribed. Silicone punctal plugs were inserted in the inferior puncta of tear deficient eyes non-responsive to the lubricant therapy described above.

Assessments

The following assessments were performed on each patient before surgery and at two weeks, and one, three and six months post-LASIK with the results recorded in the clinical database:

1. **Fluorescein break-up time** (FBUT): a measure of tear film stability, was performed using the method described by Cho and Brown.[19]
2. **Schirmer I test** (Colorbar, Eagle Vision, Memphis USA): a measure of reflex tear secretion was performed without anaesthetic using standard methods.[20] The Schirmer test was not performed at week 2 to avoid interference with flap healing.
3. **Phenol red thread tear test** (PRT) (Zone Quick Menicon Co Ltd, Nagoya Japan): a measure of tear secretion, volume and turnover was performed using the methods previously described.[21]

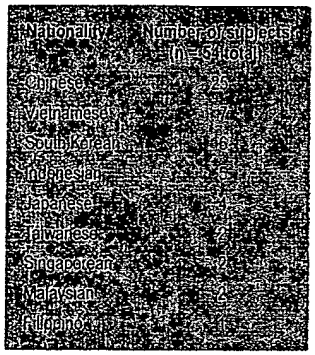


Table 1. Nationality of ancestry in Asian patient group

4. **Ocular surface staining:** fluorescein ocular surface staining was graded by the Oxford grading scheme on a scale of zero to five using methods previously described.[22]
5. **Corneal sensation:** central corneal sensation was measured using the Cochet-Bonnet aesthesiometer (Luneau Ophthalmologie, Charters, France).[23]
6. **Dry eye symptoms:** dry eye symptoms were assessed using the McMonnies Dry Eye Symptom Survey, a validated dry eye symptom survey.[24] Patients were classified as having dry eye symptoms (either before or after surgery) if they reported experiencing one or more of the primary symptoms in the survey (soreness, scratchiness, dryness, grittiness, burning) occurring often or constantly.
7. **Refractive outcome:** defined as the difference between the spherical equivalent refraction and the target spherical equivalent refraction.

Patients were questioned on their history of contact lens wear. Patients were classified as contact lens wearers before surgery, if they wore lenses on a regular basis (minimum average wearing time of 30 hours per week) and had worn contact lenses for at least the past year. Occasional or intermittent contact lens wearers were regarded as non-contact lens wearers for the purpose of this study.

In accordance with standard criteria,[20] patients were diagnosed as having dry eye before or after surgery, if they experienced one or more of the McMonnies dry eye primary symptoms occurring 'often' or 'constantly', their FBUT was less than 10 seconds and they had a fluorescein corneal staining score of one or more. Patients were diagnosed as having chronic dry eye if they had dry eye (according to the definition above) for a period of six months or more after surgery. The six-month cut-off point was chosen because at six months, the majority of studies indicate that dry eye parameters such as dry eye symptoms,[8] tear film stability,[8,10] ocular surface staining,[8,9] tear volume,[8] tear secretion[9,10] and corneal sensation[8,9] have returned to pre-operative levels.

Statistical analysis

Parametric tests were used to analyse refractive data. Other ocular variables were analysed using non-parametric tests because of the non-normal distribution of the data. Comparisons between groups and between variables were made using the Pearson Chi Square Test for categorical data and the ANOVA or the Kruskall-Wallis ANOVA tests for continuous data. Differences were considered significant when $p < 0.05$.

RESULT

Overall patient demographics

For the 932 patients, the mean spherical equivalent refraction was -4.6 ± 2.8 D (sphere -3.78 ± 2.19 D [minimum -1.00; maximum -16.50], cylinder -0.68 ± 0.91 D [minimum 0.00; maximum -6.50]). Mean ablation depth for all patients was 59 ± 27 µm (minimum 15; maximum 161).

Mean patient age was 36 ± 9 years (minimum 18; maximum 65) and 56 per cent (522/932) of patients were female. Before LASIK surgery five per cent (47/932) of the patients were diagnosed with dry eye and a further 16 per cent (151/932) reported dry eye symptoms but did not have significant dry eye signs. Following surgery, seven per cent (65/932) of patients were affected by chronic dry eye.

Comparison of patient characteristics: Asian and Caucasian groups

Asian patients comprised six per cent (54/932) of patients. Chinese patients formed 46 per cent of the Asian group. The breakdown of nationalities of the Asian patients is given in Table 1. Patient characteristics for Asian and Caucasian patients are presented in Table 2. The Asian group had significantly more females, higher attempted refractive corrections and greater total ablation depths compared to the Caucasian group. There were significantly more contact lens wearers in the Asian group. The percentage of subjects diagnosed with dry eye before surgery and the percentage receiving pretreatment was not significantly different between the groups.

Comparison of intra-operative and post-operative complications and refractive outcomes: Asian and Caucasian groups

There were no significant differences between Asian and Caucasian eyes with respect to intra-operative and post-operative complications (Table 3). The difference between the spherical equivalent of refraction and the target refractive outcome was not significantly different between Asian and Caucasian eyes at any time after surgery.

Comparison of chronic dry eye prevalence after LASIK

Asians eyes had a higher prevalence of chronic dry eye after LASIK (28 per cent [15/54] compared with five per cent [41/878] for Caucasian eyes, [$p < 0.001$]). Asian patients with chronic dry eye were predominantly female, reported dry eye symptoms, had greater ocular surface staining and poorer tear secretion, tear film stability and tear volumes before surgery (Table 4).

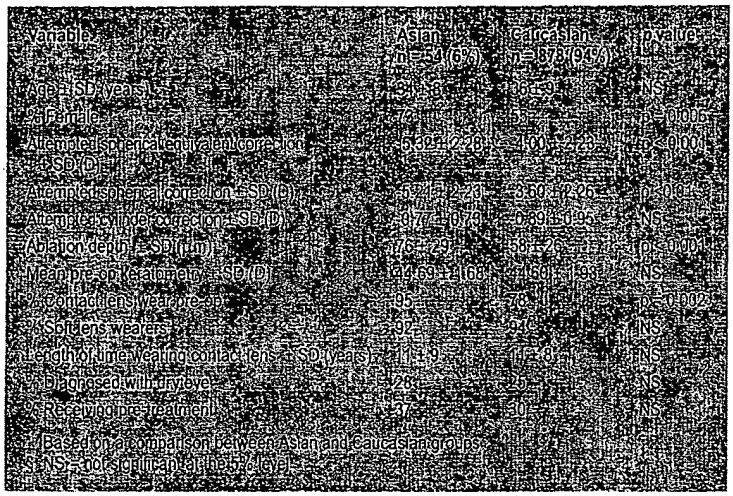
Comparison of dry eye outcomes in Asian and Caucasian groups matched for surgical ablation depth

To eliminate bias in the results due to the Asian patients having a greater pre-operative myopic correction and therefore greater total ablation depth compared to

the Caucasians, we examined a subgroup of patients where the Asian (n = 48) and Caucasian (n = 407) patients were matched for surgical ablation depth. The subject demographics of this subgroup are given in Table 5. With this adjustment for refractive ablation, the prevalence of chronic dry eye was 25 per cent (12/48) in Asian eyes and seven per cent (29/407) in Caucasian eyes. Comparisons of the prevalence of dry eye symptoms and of tear film and ocular surface parameters before and after surgery for the surgical ablation depth matched Asian and Caucasian groups are given in Table 6.

Before LASIK, there were no significant differences in the percentages of patients in the Asian and Caucasian groups reporting dry eye symptoms often or constantly. Dry eye symptoms were significantly more prevalent in Asian eyes at all times after surgery. Tear film stability and volume were significantly reduced before surgery and at all times after surgery in Asian eyes. Ocular surface fluorescein staining was greater in Asian eyes before surgery and at all times after surgery. Compared with Caucasian eyes, tear secretion was significantly reduced at one month and three months after surgery in the Asian group. Central corneal sensation was significantly reduced in Asian eyes at three and six months compared with Caucasian eyes.

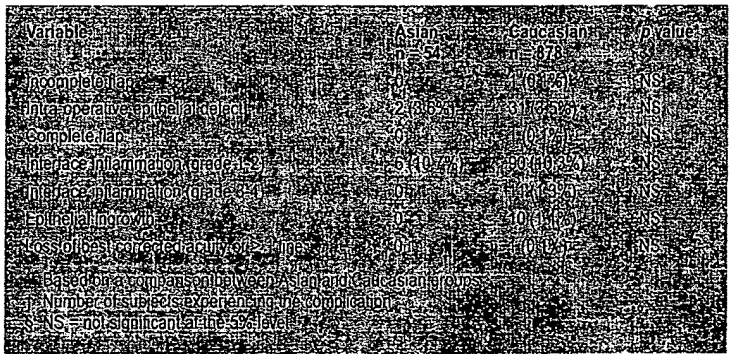
Asian eyes had a slower recovery to pre-operative values for some of the pre-operative dry eye parameters (Table 6). In Asian eyes, dry eye symptoms were more prevalent compared to pre-operative values at all times after surgery. In Caucasian eyes, the prevalence of dry eye symptoms was significantly increased at months 1, 3 and 6 after surgery compared to pre-operative values. Ocular surface staining was significantly increased at all times after surgery in Asian eyes but increased only at week 2 after surgery in Caucasian eyes. The PRT test was significantly reduced from pre-operative values at week 2 in Caucasian eyes and week 2, month 1 and month 3 in Asian eyes. Corneal sensation recovered to pre-operative levels by month 6 in Caucasian eyes whereas in the Asian group the recovery of corneal sensation did not occur until month 12.



Variable	Asian n = 48 (%)	Caucasian n = 378 (94%)	p value*
Age ± SD (years)	31 ± 8	30 ± 9	NS
Female	71	55	p = 0.005
Attempted spherical equivalent correction ± SD (D)	-5.38 ± 2.28	-4.01 ± 2.25	p = 0.001
Attempted spherical correction ± SD (D)	-5.21 ± 2.28	-3.80 ± 2.26	p = 0.001
Attempted cylinder correction ± SD (D)	-0.77 ± 0.78	-0.89 ± 0.95	NS
Ablation depth ± SD (μm)	76 ± 29	58 ± 26	p = 0.001
Mean pre-op keratometry ± SD (D)	44.09 ± 1.66	43.61 ± 1.93	NS
Contact lens wearers pre-op	85	78	p = 0.002
Soft lens wearers	92	94	NS
Length of time wearing contact lens ± SD (years)	11 ± 9	11 ± 8	NS
Diagnosed with dry eye	28	20	NS
Received pre-treatment	10	7	NS

* Based on a comparison between Asian and Caucasian groups
NS = not significant at the 5% level

Table 2. Comparison of pre-operative demographics and tear film and ocular surface variables in Asian and Caucasian eyes (all subjects included)



Variable	Asian n = 54	Caucasian n = 878	p value*
Incomplete flap	0	1 (0.1%)	NS
Intra-operative epithelial defect	2 (3.7%)	31 (3.5%)	NS
Complete flap	0	0 (0%)	NS
Interface inflammation (grade 1-2)	5 (10.2%)	90 (10.3%)	NS
Interface inflammation (grade 3-4)	0	13 (1.5%)	NS
Epithelial ingrowth	0	2 (0.2%)	NS
Loss of ≥ 1 corrected acuity lines	0	1 (0.1%)	NS

* Based on a comparison between Asian and Caucasian groups
Number of subjects experiencing the complication
NS = not significant at the 5% level

Table 3. Comparison of inter-operative and post-operative complications in Asian and Caucasian eyes

DISCUSSION

To our knowledge, this is the first study that directly compares LASIK outcomes in Asian and Caucasian eyes. This study has demonstrated that Asian patients have a significantly increased risk of experiencing chronic dry eye after LASIK. It also suggests that the dry eye after LASIK is more severe and more sustained in Asian compared to Caucasian patients. These findings are due, at least in part, to Asian eyes having higher myopic corrections and therefore requiring greater refractive

Pre-operative variable	Asian patients with chronic dry eye n = 15 (28%)	Asian patients no chronic dry eye n = 39 (72%)	p value*
% Female	87	68	p = 0.005
Age ± SD (years)	33 ± 10	34 ± 8	NS
Pre-operative spherical equivalent refraction ± SD (D)	-5.59 ± 2.77	-5.76 ± 2.38	NS
Total ablation depth ± SD (µm)	75 ± 26	80 ± 30	NS
% Contact lens wear	88	95	NS
Duration of contact lens wear ± SD (years)	11 ± 8	13 ± 9	NS
% Dry eye symptoms	80	41	p = 0.002
Schirmer test ± SD (mm/5 mins)	4 ± 3	16 ± 10	p = 0.01
BUT test ± SD (mm/15 s)	5 ± 3	18 ± 17	p = 0.02
FBUT ± SD (s)	4 ± 3	23 ± 9	p = 0.04
Corneal sensation ± SD (mm)	56 ± 13	56 ± 11	NS
Staining score ± SD	1.3 ± 2.5	0.04 ± 0.3	p = 0.002

*Based on a comparison between Asian patients with and without chronic dry eye
NS = not significant at the 5% level

Table 4. Association of chronic dry eye after LASIK in Asian eyes with pre-operative variables

Pre-operative variable	Asian n = 48	Caucasian n = 407	p value*
% Female	71	60	p = 0.04
Age ± SD (years)	35 ± 9	36 ± 9	NS
Pre-operative spherical equivalent refraction ± SD (D)	-5.62 ± 2.25	-5.66 ± 2.07	NS
Total ablation depth ± SD (mm)	77 ± 29	76 ± 27	NS
% Contact lens wear	90	89	NS
Length of time in contact lens wear ± SD (years)	12 ± 7	12 ± 9	NS
% Diagnosed with dry eye	27%	22%	NS

*Based on a comparison between Asian and Caucasian groups
NS = not significant at the 5% level

Table 5. Patient demographics of ablation depth matched Asian and Caucasian subgroups

ablations to achieve emmetropia. We have previously demonstrated deeper stromal ablations to be a risk factor for chronic dry eye after myopic LASIK.[25] Deeper stromal ablations result in a slower return of corneal sensation to levels observed before surgery.[3,26] This loss of sensory innervation has been identified as one of the leading causes of tear film and ocular surface anomalies after LASIK surgery.[3,7,9,27]

After controlling for surgical ablation depth, other pre-operative characteristics of our Asian group could predispose this group to a higher likelihood of developing chronic post-LASIK dry eye. The Asian group had significantly more females, more contact lens wearers, lower pre-operative tear volume, less tear film stability and greater pre-operative ocular surface staining scores compared to the Caucasian group. All of these factors have been associated with a delayed recovery of corneal sensation to pre-operative levels.[4,5,9,11,25] Indeed, corneal sensation was decreased in the Asian group compared to the Caucasian group at all times, with these differences being significant at months 3 and 6 after surgery.

Additionally, anatomical differences between the Asian and Caucasian eye may produce a more severe and sustained post-LASIK dry eye. The prevalence of dry eye symptoms and diagnosed dry eye in the general population appears to be greater in Asians than in Caucasians. For example, the dry eye prevalence determined by diagnostic criteria of chronic dry eye symptoms, ocular surface staining and tear film instability or insufficiency in Japanese patients presenting to an ophthalmology clinic was 17 per cent.[28] Australian and Danish studies using similar dry eye diagnostic criteria to the Japanese study gave dry eye prevalence of 11 per cent and eight per cent, respectively.[29,30] Self-reporting of one or more dry eye symptoms experienced often or all the time occurred in 33 per cent of 598 Japanese patients[31] and 18 per cent of 1,548 Australian subjects.[29]

In elderly patients (65 years or older), dry eye symptoms are also more prevalent in Asian participants. The prevalence of self-reported dry eye symptoms occurring often or constantly was 34 per cent in 1,361 elderly Taiwanese residents[32] and 15 per cent in 2,420 elderly US residents.[33] A large scale study involving nearly 39,876 participants in the US Women's Health Study aged 45 to 84 years, determined that compared to Caucasians, Asian participants were more likely to report severe dry eye symptoms (odds ratio 1.77, confidence interval 1.17-2.69).[34] While several authors have commented on the greater prevalence of dry eye in Asian eyes, they have been unable to offer any real explanation other than to state that the differences may be due to racial and/or environmental

factors and that further research is required.[32,34]

Few published studies have compared dry eye parameters between Asian and Caucasian subjects. Cho and Brown[19] found that Asians (Hong Kong Chinese) had significantly lower FBUT (mean eight seconds) compared to 11 to 15 seconds for Caucasian eyes. These researchers attributed the lower tear film stability in Asian eyes to differences in the eyelid anatomy and their interactions with the tear film.[19] No significant differences in tear volume measured by the PRT test were found between young normal non-contact lens wearing Asian (Japanese) and Caucasian (US) eyes, although the Japanese group had a lower mean PRT test value (18.8 ± 8.6) versus. (23.9 ± 9.5).[35] We also found that our Asian patients had significantly lower PRT and FBUT than our Caucasian patients at all times before and after surgery.

Blink rates and completeness of blinking can significantly affect tear film dynamics and ocular surface health.[20,29] Differences in blink rates between Asian and Caucasian eyes have not been evaluated but it is our observation that our Asian patients, both before and after surgery, have a lower blink rate and a greater tendency to incomplete blinking. This would produce the characteristic band of inferior staining observed in our Asian patients with chronic post-LASIK dry eye (Figures 1 and 2).

We feel that the blinking and lid surfacing anomalies observed in Asian eyes are due to anatomical differences in the eyelid and orbit, possibly exacerbated by long-term contact lens wear, which is acknowledged to cause blinking anomalies,[20] and the delayed return to pre-operative values for corneal sensation in Asian eyes. Toda and colleagues[10] found that blink rates after LASIK were reduced at months 3, 6 and 12 after LASIK in their Japanese subject group. To date, no published study has evaluated blink rate in Caucasians after LASIK. Therefore, further studies to compare blink rates in Asians and Caucasians before and after LASIK are warranted.

Surgical trauma when cutting the flap is another potential factor contributing to

Dry eye assessments	Time from surgery	Asian n = 48	Caucasian n = 407	p value[a]
Dry eye symptoms ± SD	Pre-op	23 ±	20 ±	NS
	Week 2	51 ±	29 ±	p = 0.001
	Month 1	50 ±	32 ±	p = 0.007
	Month 3	48 ±	38 ±	p = 0.041
	Month 6	55 ±	39 ±	p = 0.001
	Month 12	43 ±	29 ±	p = 0.009
FBUT ± SD (seconds)	Pre-op	6 ± 3	8 ± 4	p = 0.02
	Week 2	3 ± 1	6 ± 3	p = 0.02
	Month 1	3 ± 3	6 ± 3	p = 0.006
	Month 3	4 ± 3	6 ± 5	p = 0.03
	Month 6	4 ± 3	7 ± 5	p = 0.02
	Month 12	4 ± 2	7 ± 5	p = 0.006
PRT ± SD (mm/5 min)	Pre-op	17 ± 8	20 ± 8	p = 0.01
	Week 2	14 ± 7	16 ± 8	p = 0.04
	Month 1	12 ± 9	16 ± 8	p = 0.003
	Month 3	13 ± 5	16 ± 8	p = 0.006
	Month 6	16 ± 8	19 ± 8	p = 0.06
	Month 12	19 ± 7	24 ± 8	p = 0.005
Schirmer 1 ± SD (mm/5 min)	Pre-op	15 ± 8	16 ± 8	NS
	Month 1	6 ± 8	11 ± 8	p = 0.009
	Month 3	9 ± 5	12 ± 11	p = 0.03
	Month 6	13 ± 9	15 ± 10	NS
	Month 12	14 ± 10	16 ± 9	NS
Staining score ± SD	Pre-op	0.5 ± 1.6	0.3 ± 1.0	p = 0.04
	Week 2	1.7 ± 3.0	0.6 ± 1.8	p < 0.001
	Month 1	1.1 ± 2.7	0.5 ± 1.7	p = 0.008
	Month 3	0.9 ± 1.8	0.5 ± 1.7	p = 0.03
	Month 6	1.1 ± 1.9	0.4 ± 1.4	p = 0.005
	Month 12	1.0 ± 2.1	0.4 ± 1.4	p < 0.001
Corneal sensation ± SD (mm)	Pre-op	5.3 ± 0.6	5.4 ± 1.0	NS
	Week 2	0.3 ± 1.6	0.5 ± 1.8	NS
	Month 1	1.0 ± 1.9	1.1 ± 2.0	NS
	Month 3	2.2 ± 2.1	3.4 ± 2.0	p = 0.03
	Month 6	3.8 ± 2.0	4.9 ± 1.8	p = 0.04
	Month 12	4.7 ± 2.1	5.1 ± 1.5	NS

[a] Based on a comparison between Asian and Caucasian patient groups
NS = not significant at the 5% level
↑ Significantly increased (at the 5% level) from pre-operative value
↓ Significantly decreased (at the 5% level) from pre-operative value

Table 6. Comparison of dry eye assessments before and after myopic LASIK surgery in Asian and Caucasian groups matched for pre-operative refractive target and total laser ablation depth

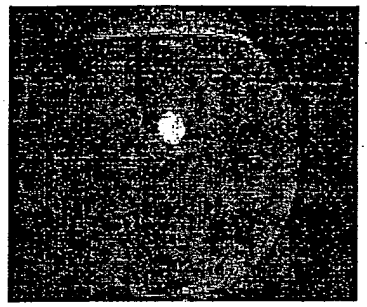


Figure 1. Chronic LASIK dry eye in a female Asian patient at nine months post LASIK for -11 D myopic correction. There is significant inferior punctate epitheliopathy and a less severe band of staining superior to the central ablation zone.

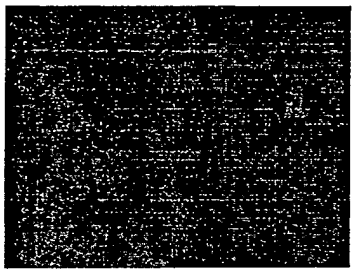


Figure 2. Significant inferior punctate epitheliopathy in an Asian eye with inferior entropion and trichiasis one month post-LASIK. Contact lens wear before surgery masked the condition.

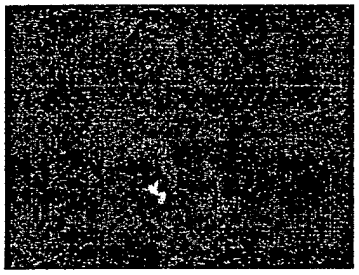


Figure 3. Diffuse staining in a female Asian patient at week 2 after LASIK for -6 D myopic correction. The patient had not been using post-operative lubrication routinely.

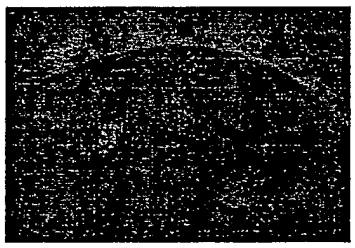


Figure 4. Superior entropion and trichiasis masked by contact lens wear in a pre-operative LASIK candidate. The patient was advised to remain in contact lenses or consider entropion repair prior to undergoing any form of keratorefractive surgery.

ocular surface damage and dry eye after LASIK.[36] In general, Asian eyes have a shallower orbit, smaller vertical orbital dimensions and differences in the upper eyelid anatomy compared to Caucasians. Asian eyes also have narrower palpebral fissures.[37,38] These factors can predispose Asian eyes to greater likelihood of flap cut problems.[38] Asano-Kato and co-workers[39] found that Asian eyes were more disposed to problems with suction with the microkeratome. They concluded that the narrow palpebral fissures commonly found in Asian populations might be a risk factor for insufficient fixation of a microkeratome in LASIK. Although our Asian patients did not experience a higher incidence of flap cut complications, our surgeon did find that intra-operative preparation for the flap cut took longer for Asian eyes compared with Caucasian eyes, due to these eyelid and orbital issues. Longer intra-operative times and a tight fit with the suction ring and keratome, even in the absence of flap cut complications, could add to the intra-operative damage to the ocular surface and the perilimbal goblet cell loss and be a contributing factor to the high degree of ocular surface staining seen after LASIK in Asian patients (Figure 3).

Epiblepharon and entropion can be features of Asian eyelids and, in severe cases, are associated with trichiasis and corneal punctate epithelial erosions.[37] Contact lens wear will mask the effects of trichiasis (Figures 4) and these patients may need to consider eyelid surgery to correct the eyelid anomalies before LASIK if significant trichiasis and punctate erosions are present, or alternatively remain in their contact lenses if ocular health permits.

The greater prevalence, duration and severity of dry eye in our Asian group is concerning, particularly given that we employ intensive ocular surface management strategies before, during and after surgery in an attempt to reduce the incidence and severity of LASIK induced dry eye,[8,25,36] and given that the prevalence and severity of myopia in Asian eyes is increasing. Asian LASIK candidates with increased risk of developing dry eye (females, dry eye before surgery, higher attempted corrections and long-term contact lens wearers) should be counselled pre-operatively regarding their increased risk of developing chronic dry eye after LASIK and alternative corrective options should be considered. It may be prudent for Asian patients who are safely and comfortably wearing contact lenses to remain in their contact lenses or to consider photorefractive keratectomy which has a lower long-term incidence of chronic dry eye symptoms and signs.[1,7,40]

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antibiotics. In one eye, a scarring process slightly decreased BSCVA.

Our cases illustrate that even when LASIK is performed in a sterile manner, as in intraocular surgery, a risk of pneumococcal keratitis still remains. Patients need to be informed of this potential risk before LASIK. Surgeons should be alert in such cases to provide prompt treatment. When appropriate therapy is started early, the clinical picture improves within days and achieved BSCVA is ≥20/25.

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Retinal Phlebitis After LASIK

Jane-Ming Lin, MD; Yi-Yu Tsai, MD

ABSTRACT

PURPOSE: To report a case of retinal phlebitis with cystoid macular edema in both eyes 8 weeks after LASIK.

METHODS: A 30-year-old woman underwent bilateral myopic LASIK. Eight weeks postoperatively, the patient experienced blurred vision in the left and right eyes. Fundus examination showed focal whitish patches in the parafoveal and juxtafoveal areas and lack of foveal reflex in both eyes. A diagnosis of retinal phlebitis with cystoid macular edema was made, which was treated with oral corticosteroids with tapering dose.

RESULTS: Visual acuity returned to normal and the whitish fundus patches decreased in number and size in both eyes.

CONCLUSIONS: Surgeons should be aware of potential risks and retinal complications associated with LASIK. [*J Refract Surg*. 2005;21:501-504.]

The increasing number of LASIK surgeries for myopia has led to an awareness of the potential hazards and retinal complications of this procedure. Reported posterior segment complications include rhegmatogenous retinal detachment,[1] choroidal infarction,[2] macular, submacular, or premacular hemorrhage,[1,3] macular hole,[4] central or branch retinal vein occlusion,[5] retinal nerve fiber layer defects,[6] optic neuropathy,[7] and cystoid macular edema.[8]

We report a 30-year-old woman who underwent bilateral myopic LASIK. Retinal phlebitis with cystoid macular edema developed in both eyes 8 weeks postoperatively. Visual acuity returned to normal after treatment with oral steroids.

CASE REPORT

A 30-year-old woman with an insignificant medical

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The authors have no proprietary interest in the materials presented herein.

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and ocular history underwent bilateral myopic LASIK. Before LASIK, refractive error was −7.50 −3.25 × 15° in the right eye and −8.00 −2.75 × 140° in the left eye. Best spectacle-corrected visual acuity (BSCVA) in both eyes was 20/20. Postoperative uncorrected visual acuity (UCVA) was 20/20 in both eyes.

Eight weeks after surgery, the patient experienced onset of blurred vision in the left eye. Three days later, the same symptom occurred in the right eye.

On initial evaluation, BSCVA was 20/100 in the right eye and 16/200 in the left eye. Anterior segment examination was unremarkable except for a well-healed LASIK flap and trace subepithelial haze in both eyes. Intraocular pressure (IOP) was normal. The vitreous was free of cells. Fundus examination showed several focal whitish patches in the parafoveal and juxtafoveal areas and lack of foveal reflex in both eyes (Fig 1A). Fluorescein angiography revealed late staining of the dye in the wall of the dilated venules (the left eye more than the right eye) and mild cystoid macular edema bilaterally (Fig 1B).

Visual field testing with Humphery Central 30-2 Threshold Test (Humphery Instruments, San Leandro, Calif) was normal in the right eye, but demonstrated a paracentral scotoma in the left eye. No other extraocular lesion was observed. Results of laboratory studies were normal. Therefore, diagnosis of retinal phlebitis in both eyes was made. The patient was treated with oral corticosteroids with tapering dose.

On subsequent examinations, visual acuity continued to improve. One month after treatment, UCVA was 20/30 in the right eye and 20/200 in the left eye. Best spectacle-corrected visual acuity improved to 20/20 in the right eye and 20/25 in the left eye. Whitish fundus patches decreased in number and size in both eyes. Fluorescoin angiography demonstrated moderate resolution of cystoid macular edema and no venous dye staining in both eyes. Visual field in the left eye also returned to normal.

Two months after treatment, UCVA was 20/20 in the right eye and 20/30 in the left eye (BSCVA 20/20). Fundus examinations revealed faint whitish patches and normal foveal reflex in both eyes. On final examination 6.5 months after treatment, UCVA had returned to 20/20 in both eyes. Fundus examinations in both eyes were essentially unremarkable except for some mottling changes of retinal pigment epithelium at the posterior pole of the right eye (Fig 2A). Fluorescein angiography of both eyes revealed no venous dye staining or cystoid macular edema (Fig 2B).

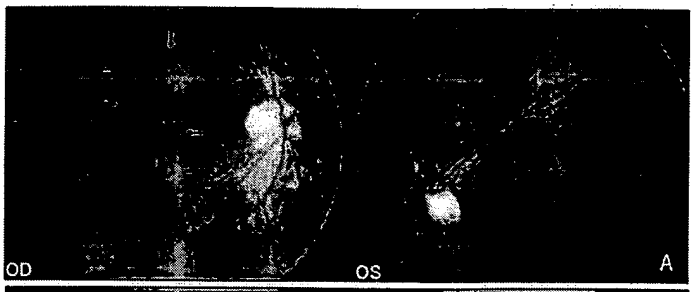
DISCUSSION

Retinal vasculitis has posed a difficult diagnostic problem for ophthalmologists for many years. It is a sight-threatening inflammatory disease with an unknown etiology and pathogenesis. Retinal veins, capillaries, and arterioles may be involved and veins are most commonly affected. It may occur as a complication of infection, neoplasm, degenerative disorders, or be associated with systemic inflammatory diseases (eg, Behçet's syndrome, sarcoidosis, uveomeningitis, HLA-B-27 related arthritis) or isolated findings.[9] In a study by Graham et al[9] of 150 patients with idiopathic retinal vasculitis, 67 (45%) patients had isolated retinal vasculitis and 83 (55%) patients had retinal vasculitis associated with systemic inflammatory disease. In our patient, we found no evidence of associated systemic inflammatory disease, infection, or neoplasm. The patient's reduction in visual acuity was not caused by myopic subretinal neovascularization or hemorrhage but by cystoid macular edema. No previous ocular disease was reported that could have explained cystoid macular edema, and no events (trauma or other inflammation) other than LASIK occurred. Therefore, we believe this patient's retinal phlebitis with cystoid macular edema may be associated with LASIK.

The rise and decompression of IOP during suction and the acoustic shock waves created by the laser might have been responsible for the retinal phlebitis seen in our patient.[1] An IOP of at least 65 mmHg is necessary to create a corneal flap with the microkeratome. During this time, the shape of the anterior segment may change rapidly and structures posterior to the suction ring are also compressed in sequence.[10,11] When the suction stops and the suction ring is released, ocular decompression leads to dynamic equatorial elongation and anterior-posterior contraction.[10] This barotrauma is analogous to what happens in closed-eye injury[12,13] and can alter delicate retinal structures, especially small vessels, and induce vitreoretinal traction at the vitreous base and posterior pole.[10,14] Sudden elevation of IOP also disturbs the retinal circulation and increases venous pressure, which results in retinal ischemia. All of these conditions may aggravate the original impaired blood-retinal barrier in highly myopic eyes and increase vascular permeability,[15] leading to the loss of integrity of tight junctions of endothelial cells.

Laser in situ keratomileusis-induced shock waves can generate up to 100 atm.[16] Although the pressure decreases steadily to values below 10 bars toward the retina,[1] we believe it may still cause mechanical stress to the retina, resulting in structural damage and intraocular inflammation. In addition, total energy and duration increase with higher refractive error and the effect of mechanical stress may be more severe in higher myopia, which has more liquefaction of the posterior vitreous gel.[17]

Of course, one case report does not prove a cause-



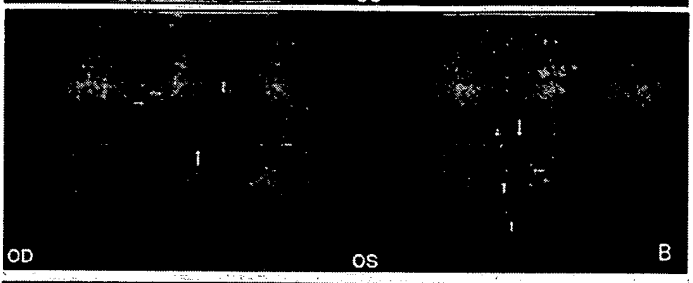
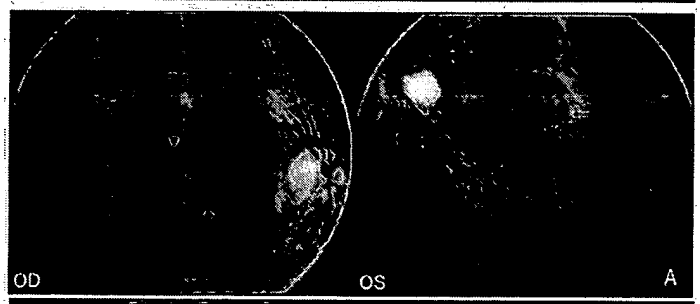


Figure 1. Fundus photograph and fluorescein angiogram 8 weeks after LASIK. **A)** Fundus photographs showed several focal whitish patches in the parafoveal and juxtafoveal areas (arrows) and lack of foveal reflex in both eyes. **B)** Late phase of fluorescein angiography revealed staining of the dye in the wall of the dilated venules (small arrows, the left eye more than the right eye) and mild cystoid macular edema bilaterally (large arrows).



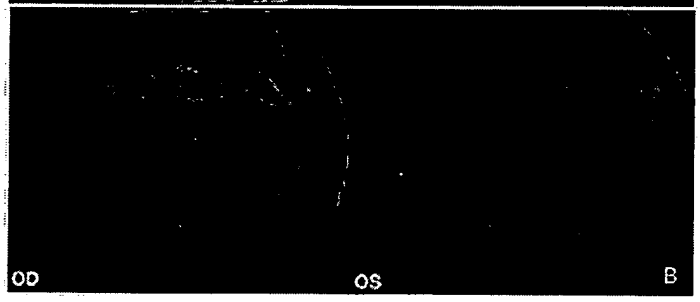


Figure 2. Fundus photograph and fluorescein angiogram 6.5 months after treatment. **A)** Fundus photographs in both eyes were essentially unremarkable except for some mottling retinal pigment epithelium at the posterior pole of the right eye (arrowhead). Normal foveal reflex was noted in the left eye (arrow). **B)** Fluorescein angiography revealed no venous dye staining or cystoid macular edema.

and-effect relationship between LASIK and retinal phlebitis. However, this report should alert ophthalmologists to the importance of determining the risk factors, performing echography of vitreous, indirect ophthalmoscopy with scleral depression, and possibly photography and fluorescein angiography of macula to determine whether the LASIK procedure itself might exacerbate the original pathologic changes of myopia.

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